TEXAS Health and Human Services | Texas Department of State Health Services

Texas Perinatal Hepatitis B Prevention Program Manual

Revised 05/2024

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Quick Reference Guide

Maternal hepatitis B surface antigen (HBsAg) testing

According to state law, all pregnant women must be screened for hepatitis B infection at the first prenatal visit and again upon admittance for delivery for each pregnancy.

Vaccination of infants at birth

Born to a woman who is HBsAg-positive

- Hepatitis B Immune Globulin (HBIG) and Hepatitis B vaccine within 12 hours of birth (regardless of birthweight).
- For pre-term or low birthweight infants less than 2,000 grams (less than 4.4 pounds), the hepatitis B vaccine series should be re-initiated at one month of age.

Born to a woman whose HBsAg status is unknown

- Hepatitis B vaccine within 12 hours of birth.
- Mother should be tested immediately to determine HBsAg status.
- If mother is determined to be HBsAg-positive or refuses to be tested, immediately administer HBIG to the infant before hospital discharge.

  Note: HBIG should not be administered more than seven days after birth.
- Infants weighing less than 2,000 grams (less than 4.4 pounds) and born to HBsAg-positive women should receive HBIG and vaccine within 12 hours of birth. The hepatitis B vaccine series should be re-initiated at one month of age.

Born to a woman who is HBsAg-negative

- All medically stable infants 2,000 grams or more (4.4 pounds or more) should receive hepatitis B vaccine within 24 hours of birth.
- Pre-term or low birthweight infants of less than 2,000 grams (less than 4.4 pounds) born to HBsAg-negative mothers can defer vaccination until one month of age or hospital discharge.

Reporting

- All HBsAg-positive pregnant women must be reported within one week to the DSHS PHR or LHD or the DSHS Immunization Section PHBPP.
- Infants born to HBsAg-positive pregnant women and household contacts 24 months of age or younger should be identified, reported to the DSHS PHR or LHD within one workday, and case managed by program staff.

Hepatitis B vaccine series

- All infants should complete the Hepatitis B vaccine series with either a single-antigen or combination vaccine, according to the Advisory Committee on Immunization Practices (ACIP)-recommended hepatitis B vaccination schedule.

Hepatitis B Post-Vaccination Serologic Testing (PVST)

- All infants born to HBsAg-positive pregnant women or infants born to women whose HBsAg status remains unknown indefinitely (e.g., safe surrender infants) should be tested for HBsAg and anti-HBs after completion of the vaccine series.
- PVST testing should be done one to two months after completion of the vaccine series, but no earlier than nine months of age.
- For infants who complete the vaccine series on time at six months of age, PVST testing should be done at nine months of age.

Chapter 1: Program Background and Introduction

Background

Screening of all pregnant women for hepatitis B has been recommended since 1991 by the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Advisory Committee on Immunization Practices (ACIP). On June 18, 1999, Governor George W. Bush signed legislation requiring pregnant women in Texas to be screened for HBV infection at their first prenatal examination and at delivery for each pregnancy. This law became effective September 1, 1999; and applies to the provider who attends to a pregnant woman during gestation and/or at delivery of her infant[1]. In July 2019, the U.S. Preventive Services Task Force (USPSTF) reiterated the importance of screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit by giving it an "A" recommendation. This means there is significant evidence to prove that this screening is beneficial.

The Texas Department of State Health Services (DSHS) Perinatal Hepatitis B Prevention Program (PHBPP) was first implemented in 1991 in Harris, Tarrant, and Dallas counties, as well as the cities of Houston and San Antonio. In 2001, the program was expanded to provide services to the entire state.

The program was tasked with six key responsibilities:

- Identify all HBsAg-positive pregnant women and their infants in Texas
- Assure administration of Post-Exposure Prophylaxis (PEP) is given within 12 hours of birth to exposed infants
- Identify and vaccinate susceptible household contacts 24 months of age and younger and ensure adult household and sexual contacts are referred out
- Ensure hepatitis B vaccine birth doses are universally administered
- Assure completion of hepatitis B vaccine series and PVST of exposed infants
- Conduct active surveillance, quality assurance, outreach and education to improve PHBPP program outcomes

Although vaccine prevention and awareness has steadily increased since the start of the program, it was estimated in 2021 by the Centers for Disease Control and Prevention (CDC) that 882–1,189[2] infants were born to Hepatitis B Surface Antigen (HBsAg) positive women in Texas. However, the Perinatal Hepatitis B Prevention Program (PHBPP) identified 550[3] infants as being born to HBsAg-positive women in 2021.

In 2018, a total of 3,322 cases of acute hepatitis B were reported nationwide to the CDC, with the highest rate amongst 40-49-year-olds. From 2011-2016, rates of acute hepatitis B were repeatedly highest among persons aged 30-39 years old, however, 2017 and 2018 saw the highest rate in 40-49-year-olds. The CDC reported in 2018 that more than half of all acute hepatitis B cases were in individuals 30-49 years old.

Perinatal transmission of the hepatitis B virus (HBV) is highly efficient and usually occurs from blood exposures during labor and delivery. Although in utero transmission is rare, it does account for nearly two percent of perinatal infections in most studies. Every year, it is estimated that 25,000 infants are born to women chronically infected with hepatitis B in the U.S. Without timely Post-Exposure Prophylaxis (PEP) at birth, approximately 90% of these infants would become chronically infected and approximately 25% of the infected would die prematurely of liver failure or liver cancer.

Transmission of hepatitis B to these high-risk babies could be prevented 85-95% of the time by providing appropriate PEP within 12 hours of birth, as described in this manual. Although perinatal hepatitis B has been nationally notifiable since 1995, the reporting of cases has not been reliable for monitoring purposes.

Less than five percent of the HBV infections that occur among children are reported as cases of acute hepatitis B to the CDC because these infections in infants and children rarely produce signs or symptoms of disease until other complications arise. Infants infected during their first year of life have a 90% chance of developing a chronic HBV infection compared to only 25-50% of children infected between ages one and five years old. In contrast, less than five percent of otherwise healthy people who become infected during adulthood will develop a chronic infection. Prior to routine PEP of infants and children, cases occurring in children accounted for a disproportionate amount of the disease burden due to chronic infection.

According to the 2018 National Immunization Survey (NIS), 89.2% of Texas children aged 19-35 months, have received three or more doses of hepatitis B vaccine.
The 2018 NIS results also show that 79.4% of children in Texas received the first dose of hepatitis B vaccine between birth and three days of age.

The Ten Key Elements of the Perinatal Hepatitis B Prevention Program

The DSHS Immunization Section PHBPP has several important features including, but not limited to surveillance; case management; promotion of the universal birth dose and collaboration between DSHS Public Health Region (PHR) offices, Local Health Department (LHD) offices, medical providers and laboratories. All case management is completed by state PHBPP staff within the Texas PHBPP Salesforce database. The ten objectives of the program are listed below. All the headings are direct links to the chapters with more information.

1. Ensure all pregnant women are tested for hepatitis B surface antigen (HBsAg).

- According to Texas law, providers must screen pregnant women for hepatitis B infection at the first prenatal examination (regardless of trimester) and upon delivery, or as soon as feasibly possible thereafter
- The CDC recommends HBsAg as the preferred test for screening for HBV infection during pregnancy. ACIP also recommends HBV DNA viral load testing for HBsAg-positive pregnant women to guide antiviral therapy as needed
- HBsAg testing should be incorporated into standard prenatal testing panels used by all providers caring for pregnant women. It is recommended that the hepatitis B serologic marker (HBsAg CPT code 87341) and reason for testing (pregnancy) be specified when submitting these specimens to the laboratory
- Providers should notify all HBsAg-positive pregnant women of their positive status as soon as possible and give them a copy of the original laboratory result
- Providers should provide education to all HBsAg-positive pregnant women regarding the potential risks to their infant and what measures (e.g., HBIG, hepatitis B vaccine series, PVST) can be taken in an effort to protect the child from Hepatitis B transmission. The patient should also be informed that the DSHS PHR or LHD will be contacting them for case management
- Delivery facilities/hospitals should determine if a pregnant woman presenting to their facility was screened for HBsAg prenatally and document those results in both the mother's and infant's medical records
- Delivery facilities/hospitals must draw blood to screen for HBV infection at delivery, regardless of the result obtained at the prenatal examination
- Delivery facilities/hospitals should safeguard against errors in maternal HBsAg testing and failures in test reporting. This can be done by
    - Maintaining standing orders for immediate HBsAg testing of all pregnant women upon admission for delivery
    - Ordering admission lab tests that specify to draw "HBsAg", to avoid confusion with other hepatitis serologic markers
    - Including a copy of the original HBsAg laboratory report in the delivery record

2. Ensure reporting and case management of all HBsAg-positive women.

- All HBsAg-positive pregnant women must be reported to the DSHS Immunization Section PHBPP for case management of the mother and infant(s)
- Reporting can be accomplished by uploading information at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/

3. Ensure delivery facilities/hospitals receive all prenatal HBsAg lab reports prior to delivery.

- HBsAg test results should be uploaded at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/ used by providers to record and transmit information about care during pregnancy.
- For all pregnant women, a copy of the original HBsAg laboratory result should be transferred from the prenatal care provider to the delivery hospital with the mother's medical records
- Providers caring for HBsAg-positive pregnant women should remind delivery staff (doctors, midwives, nurses) of HBsAg-positive status during a client's pregnancy to ensure the baby receives all necessary care upon delivery

4. Ensure identification and management of infants born to HBsAg-positive women.

- Delivery facilities/hospitals should implement policies and procedures to ensure proper identification of HBsAg-positive pregnant women and their infants. (Refer to Appendix E for examples)
- All infants born to HBsAg-positive women require the administration of PEP within 12 hours of birth. Delivery facilities/hospitals must document all required information (Refer to number five under Key Elements for reporting information)
- Document proper health information on the medical data worksheet for the infant's birth certificate (hepatitis B infection during pregnancy)
- If an HBsAg-positive woman refuses PEP for her newborn, providers must ensure that the mother is informed and educated about her status and the potential consequences to her newborn(s) and the option to receive PEP up to seven days after delivery
- Document in the infant's medical record the mother's signed declination against medical advice (AMA) form (facility specific) against the medically recommended treatment for her infant(s) and all education provided regarding hepatitis B and the potential consequences to her newborn(s)

5. Ensure reporting of HBsAg-positive women and infants to the health department.

- HBsAg-positive mothers must be reported within one week at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/
- HBsAg-positive infants must be reported within one day at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/
- Delivery facilities/hospitals must report and upload all information at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/
- Maternal HBsAg status (and other serology) at time of delivery
- Prenatal Provider and Infant Provider
- Date and Time of Birth
- Birth Weight
- HBIG and Hepatitis B vaccine administration:
  - date and time
  - lot number
  - manufacturer*
  - formulation/brand name
    (i.e., Engerix-B, Recombivax HB, HepaGam HB, HyperHEP B, Nabi-HB, etc.) *

* Refer to Chapter 4, Post-Exposure Prophylaxis (PEP), for chart of manufacturers and formulations of HBIG.

6. Ensure identification and case management of infants born to women of unknown HBsAg status.

- Delivery facilities/hospitals should implement policies and procedures to ensure prompt identification and appropriate PEP administration to infants born to women of unknown HBsAg status
- An infant whose mother's HBsAg test result comes back positive should immediately receive HBIG
- Document Hepatitis B infection present during pregnancy on the medical data worksheet for the infant's birth certificate (i.e., Hepatitis B during pregnancy)

7. Upload all HBsAg positive mothers and infant information to the portal.[4] Ensure timely completion of the hepatitis B vaccine series for all infants born to HBsAg-positive women.

- Dose one should ideally be given within 12 hours of birth, and preferably no later than by hospital discharge
- Dose two should be given at one month of age, but no later than two months of age
- Dose three should be given at six months of age
  - Must be given at least eight weeks after dose two
  - At least 16 weeks after dose one
- Combination vaccines may be used to complete the series, giving the infant a total of four doses of hepatitis B vaccine
- Providers should document the date, lot number, and name/manufacturer for each dose of the hepatitis B vaccine administered to the infant
- If the child was not already registered for the Texas Immunization Registry (ImmTrac2) at birth, parental consent should be obtained. The vaccination history of the infant should then be entered into ImmTrac2 as soon as possible after each visit, this information can also be uploaded to https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/

8. Ensure timely completion of PVST for all infants born to HBsAg-positive women.

- To determine infant outcomes after appropriate PEP, PVST should be performed on all infants born to HBsAg-positive women or infants born to women whose HBsAg status remains unknown indefinitely (e.g., safe surrender infants) once
  - the infant has completed a full hepatitis B vaccine series
  - the infant is nine months of age or older
  - at least one month has passed since the infant received the final dose of a hepatitis B containing vaccine
- Providers should order:
  - HBsAg (CPT: 87340)
  - Quantitative Anti-HBs (CPT: 86137)
- Providers should document the infant's PVST results and report all results (positive or negative) at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/

9. Ensure vaccination of household contacts 24 months of age and younger.

- Household contacts 24 months of age and younger must be identified and a case management record initiated within 15 days of notification
- These contacts must be offered serologic testing (HBsAg and anti-HBs) and, if susceptible to HBV infection, initiate the hepatitis B vaccine series. If needed, both the testing and vaccine are provided free of charge through the PHBPP for all contacts 24 months of age or younger Refer to Chapter 7 for additional information
- Records for contacts 24 months of age and younger are closed upon hepatitis B vaccine series completion and PVST results. Revaccination may be needed before the case can be closed
- All contacts 24 months of age and younger, as well as all sexual partners to the HBsAg-positive mother, should be referred to a health care provider for Hepatitis B serology testing and vaccination as needed for health care evaluation

10. Ensure program quality, monitoring, and evaluation.

- Central office provides the following monthly quality assurance reports to PHR and LHD case managers:
  - Infants past due for vaccines and/or serology
  - HBsAg positive pregnant women that have exceeded their expected delivery date, based on their Estimated Due Dates (EDD)
  - Infants missing Post-Exposure Prophylaxis
  - Dashboard of PHBPP outcomes
- Central office also provides the following reports to help increase identification of HBsAg-positive pregnant women:
  - Report from the Texas National Electronic Disease Surveillance System (NEDSS) of women of childbearing age with a positive HBsAg
  - Report from the Vital Statistics Unit of women who indicated Hepatitis B was present during pregnancy on the birth certificate medical questionnaire
- The PHR/LHD case manager is responsible for reviewing all potential cases to determine eligibility weekly. Reports are sent out weekly to Regional Coordinators and additional reports can be created to assist as needed
- The LHD/PHR case managers are also responsible for providing training and education to birthing hospitals, prenatal providers, and pediatric providers. The trainings should cover the entire PHBPP program, Texas laws related to screening and reporting, and the importance of the universal Hepatitis B birth dose
- If any of the below occur, an Investigational Report form should be completed to determine the cause:
  - Missed maternal screening during pregnancy and/or at delivery
  - PVST is not done as required
  - Once the case manager has identified a missed maternal screen and/ or infant missed PEP, an Investigation form is created within Salesforce and training is required within 30 days

Chapter 2: Hepatitis B Overview

Hepatitis B Virus

The Hepatitis B Virus (HBV) belongs to the *Hepadnaviridae* family and is known to cause both acute and chronic infections in humans. The virus is found in the blood and certain body fluids (serum, semen, saliva, and vaginal secretions) of infected people. It is relatively stable and has been shown to remain infectious on environmental surfaces for more than seven days at room temperature. It is a small, round, enveloped virus with partially double-stranded circular Deoxyribonucleic Acid (DNA) and is highly infectious; the CDC has stated that percutaneous or mucosal exposure to Hepatitis B is 50 to 100 times more infectious than the Human Immunodeficiency Virus (HIV). There are nine serotypes and eight genotypes of HBV recognized worldwide.

HBV Infection

HBV infection is a major cause of acute and chronic hepatitis, cirrhosis of the liver, and liver cancer. It is the most prevalent chronic infectious disease in the world, a common cause of morbidity and mortality worldwide, and a major health problem in the U.S.
The World Health Organization (WHO) estimates that two billion people have been infected worldwide with the hepatitis B virus. The CDC estimates 257 million remain chronically infected globally while more than 887,000 people die every year due to the consequences of the virus.

The highest hepatitis B infection rates are found in sub-Saharan Africa and East Asia.
Five to ten percent of the adult population in these areas are chronically infected and most became infected during childhood. Liver cancer caused by hepatitis B is among the top three causes of cancer-related death in men, and a major cause of cancer in women in these regions. In the U.S., the CDC estimates 862,000 are living with chronic hepatitis B infection. Also, it is estimated that between 3,000-4,000 people in the U.S. die of hepatitis B-related cirrhosis each year.

After exposure, HBV is transported by the bloodstream to the liver, which is the primary site of viral replication. Infection in adults is generally self-limited, meaning the immune system can eliminate the virus from the blood and provide lasting immunity against reinfection in about 95% of cases. The remainder of adults whose immune systems do not eliminate the virus will develop a chronic, lifelong infection. A person with chronic hepatitis B is defined by the CDC as someone with HBsAg present in their bloodstream for greater than six months with continuing viral replication and persistent viremia. (See Figure 2.1.) These “chronic carriers” can transmit the virus to other individuals who are unprotected.

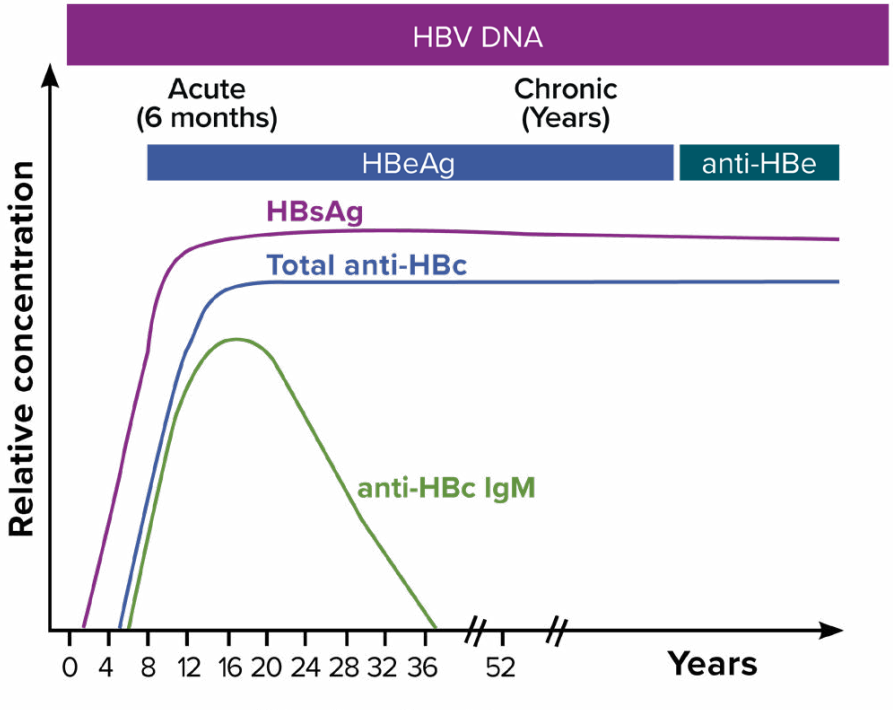


Figure 2.1. Progression to Chronic Hepatitis B Virus Infection, Typical Serologic Course

Communicability

Persons with either acute or chronic HBV infection should be considered potentially infectious.

Clinical Manifestations

The clinical manifestations of acute HBV infection are age dependent. Infants, children younger than ten years of age, and immunosuppressed adults with newly acquired HBV infection are usually asymptomatic (no symptoms). Meanwhile, approximately 30-50% of adults will show symptoms of infection. Because many infected persons are asymptomatic, they are often unaware they are infected, resulting in inadvertent transmission to others. Additionally, infected individuals can transmit the virus before symptom onset. When symptoms occur, they are not specific to hepatitis B; therefore, laboratory testing is required to distinguish HBV from other diseases.

Signs and Symptoms

The incubation period for HBV infection ranges from 60 to 150 days (average of 90 days). The preicteric (before jaundice), or prodromal, phase usually lasts from three to ten days, from initial onset of symptoms to jaundice.

Symptoms of this phase may include, but are not limited to:

- malaise
- headache
- anorexia
- myalgia
- nausea
- skin rashes
- vomiting
- arthralgia
- fever
- arthritis
- right upper quadrant abdominal pain
- dark urine starting one to two days before the onset of jaundice

The icteric (jaundice) phase is variable but usually lasts one to three weeks. It is characterized by yellowing of the skin, mucous membranes, and conjunctiva; light or gray stools; hepatic tenderness, and hepatomegaly (liver enlargement). During convalescence, malaise and fatigue may persist for weeks or months as the other signs and symptoms disappear.

Treatment

No specific treatment exists for acute hepatitis B; supportive care is the mainstay of therapy.

People who have chronic HBV infection require medical evaluation and regular monitoring. Therapeutic agents approved by the Food and Drug Administration (FDA) for treatment of chronic hepatitis B can achieve sustained suppression of HBV replication and remission of liver disease in some persons. Patients interested in treatment should seek a referral from their physician to a gastroenterologist, hepatologist, or an infectious disease specialist.

For more information on acute and chronic HBV infections, please consult The Red Book: Report of the Committee on Infectious Diseases (32nd Edition) or visit http://www.cdc.gov/hepatitis/HBV/.

Complications

The complications of chronic infection include chronic hepatitis, cirrhosis, liver failure, and hepatocellular carcinoma. Persons with chronic HBV infection are at a much higher risk of hepatocellular carcinoma than non-carriers. Approximately 25% of persons who become chronically infected die prematurely from cirrhosis or hepatocellular carcinoma. This means that approximately, 3,000 to 4,000 people die each year of HBV-related cirrhosis and approximately 1,000 to 1,500 people die each year from HBV-related liver cancer in the U.S. HBV infection is estimated to be the cause of 80% of hepatocellular carcinoma worldwide.

The complications that arise are typically associated with chronic HBV infections.
However, in a small number of cases, acute infections can result in fulminate hepatic failure and death. Fulminant hepatitis occurs in about one-two percent of acutely infected persons and has a mortality rate of 0.5–one percent, although mortality is suspected to be higher in acutely infected infants. About 200 to 300 Americans die each year of fulminant disease.

Epidemiology of the Hepatitis B Virus

Reservoir

The natural host for the hepatitis B virus is humans. The virus is not known to naturally infect animals, although some non-human primates have been infected under laboratory conditions.

Transmission

The hepatitis B virus is transmitted by parenteral or mucosal exposure to HBsAg-positive body fluids or tissues from persons who have acute or chronic HBV infection.
Parenteral exposure routes include, but are not limited to:

- intravenous (IV) drug use
- shared razor
- accidental needle sticks or sharps injuries
- contaminated multi-dose vials or medical equipment
- other breaches of blood-borne pathogen infection control practices

Mucosal exposure can occur from:

- birth
- sexual contact
- accidental blood exposure to the eyes or mouth
- shared household products (i.e., toothbrush)
- other routes if appropriate barrier precautions are not taken.

The highest concentrations of virus are in blood, serous fluids, and wound exudates; lower titers are found in other fluids, such as saliva and semen. Saliva can be a vehicle of transmission through bites, however, other types of exposure to saliva, including kissing, are unlikely modes of transmission. There appears to be no transmission of HBV via tears, sweat, urine, stool, or droplet nuclei. See Table 2.1.

As previously mentioned, HBV infection can also be transmitted through sexual contact, either heterosexual or homosexual, with an infected person. It is thought that transmission occurs among men who have sex with men (MSM), possibly via contamination from asymptomatic rectal mucosal lesions. Fecal-oral transmission does not appear to occur. Transmission in health care settings, long-term care facilities, and in-home health settings are well described due to breaches in infection control practices.

High	Moderate	Low/Non-detectable
• Blood • Serum • Wound exudates	• Semen • Vaginal fluid • Saliva	• Urine • Feces • Sweat • Tears • Breast milk

Table 2.1. Concentration of Hepatitis B Virus in Various Body Fluids

Because HBV can survive for more than seven days on environmental surfaces at room temperature, indirect inoculation of HBV can occur via inanimate objects. A ten percent bleach and water solution is recommended to decontaminate a surface after a blood spill.

Perinatal Transmission

Transmission of HBV from mother to infant during the perinatal period represents one of the most efficient modes of HBV infection. The risk of perinatal transmission is directly related to the viral load of the mother. The hepatitis B “little e” antigen (HBeAg) marker is a commonly used indicator of active viral replication and, thus, high viral load. The absence of HBeAg is generally associated with a low viral load and a lower likelihood of transmission to the infant. However, approximately 20-30% of the chronic infections in the U.S. are due to a variant of HBV called a “pre-core mutant.” This variant of the virus does not produce e-antigen while replicating. This pre-core mutant variant may have a viral load somewhere in between the e-antigen positive and e-antigen negative cases. HBV viral load can be directly measured and quantified using molecular technology. For a newborn whose mother is positive for both HBsAg and HBeAg, the risk for chronic HBV infection is 70-90% by six months of age in the absence of PEP (HBIG and hepatitis B vaccine). However, if the mother is HBsAg-positive but HBeAg-negative, the risk for chronic infection to the infant becomes less than ten percent in the absence of PEP.

The exact mechanism of transmission remains unclear, although the mode of delivery (vaginal versus C-section) does not appear to have an impact on the risk of perinatal HBV infection. Infection during pregnancy can occur during the intrauterine, or intrapartum (delivery) periods, however, HBV transmission mainly occurs during delivery. Intrauterine (in utero) transmission is relatively rare, accounting for less than two percent of perinatal infections in most studies. Hepatitis B viral DNA and HBsAg have been detected in amniotic fluid, placental cells, and vaginal secretions of HBsAg-positive women during pregnancy, as well as in the cord blood of their neonates. Postpartum transmission through exposure to infectious maternal saliva, stool, or urine is quite rare.

It has previously been believed that breastfeeding serves as an additional mechanism by which infants may acquire HBV infection. Although trace amounts of HBsAg have been found in breast milk, research strongly suggests that any risk of transmission associated with breast milk is negligible compared to the high risk of exposure to maternal blood and fluids at birth. Because there is no evidence that breastfeeding from an HBV-infected mother poses an additional risk to the infant, even without immunization, both the CDC and WHO support mothers breastfeeding in these cases. They state it is safe for an infected woman to breastfeed her child, as the benefits outweigh the risks. All mothers who breastfeed should pay particular attention to the care of their nipples to avoid any cracking and bleeding.

Other Risk Factors Associated With Hepatitis B

- People born in Asia, Africa, and other regions with moderate or high rates of hepatitis B (See Figure 2.2.)
- Unvaccinated people whose parents are from regions with high rates of hepatitis B
- Anyone having sex with a person infected with hepatitis B
- People who live with someone with hepatitis B
- Men who have sexual encounters with other men (MSM)
- People who inject drugs
- People with HIV infection
- People on hemodialysis
- Health care workers

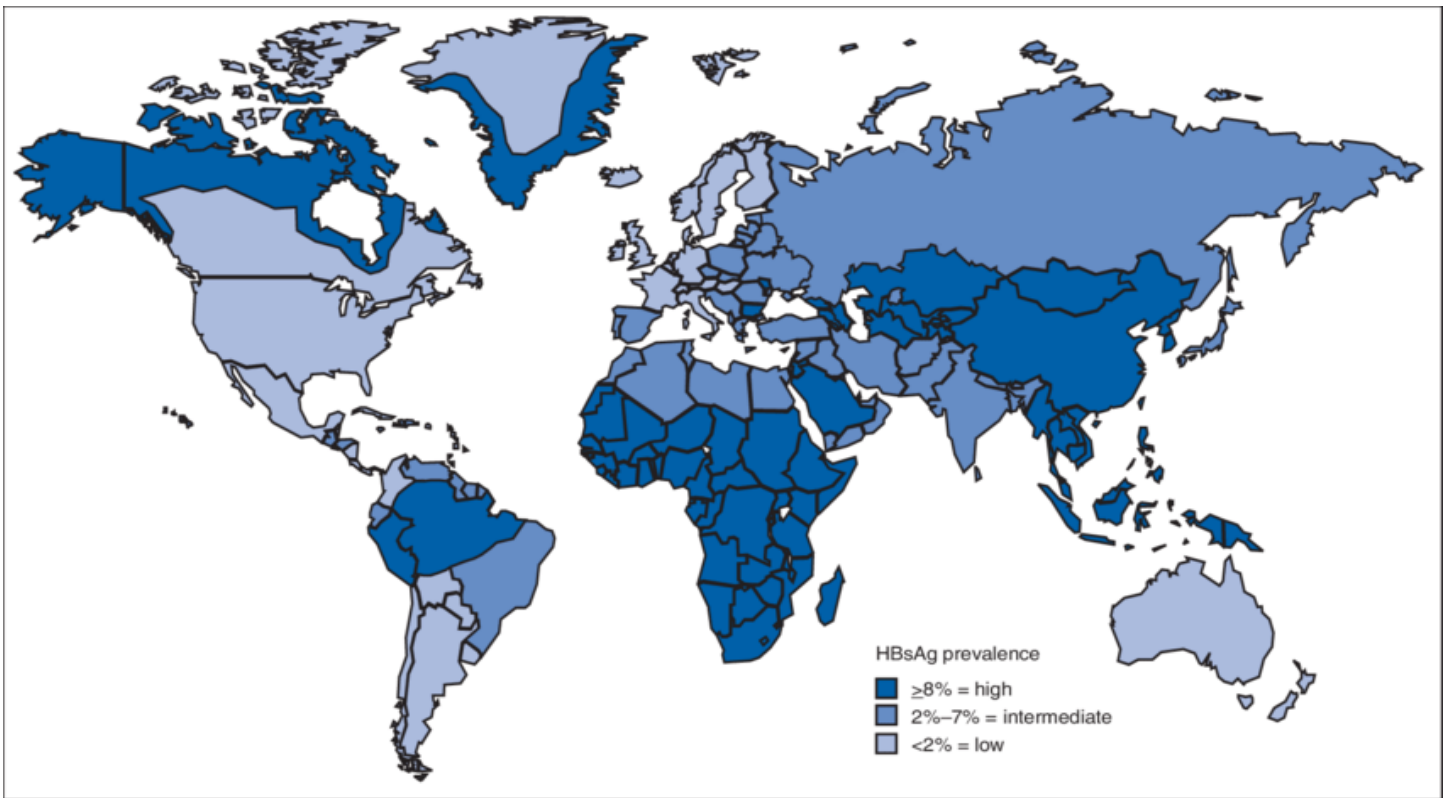


Figure 2.2. Geographic Distribution of Chronic HBV Infection

HBV Laboratory Testing

There are several antigenic components of the virus that can result in a variety of positive laboratory tests at different points in an infection.

The HBsAg is found on the surface of the virus and can be identified in serum samples 30-60 days after exposure to the virus. This component of the virus is not infectious itself, but its presence in the blood indicates that the complete virus is present, and that the person can transmit the virus to others. Once the immune system detects the HBsAg component of the virus, whether through acute infection or after vaccination, it begins to develop antibodies (anti-HBs). The presence of anti-HBs in the serum indicates immunity to the virus. Anti-HBs may also be referred to as hepatitis B surface antibody (HBsAb), which can easily be confused with HBsAg. Available laboratory testing attempts to detect these various components and antibodies as they become active. (See Figure 2.3)

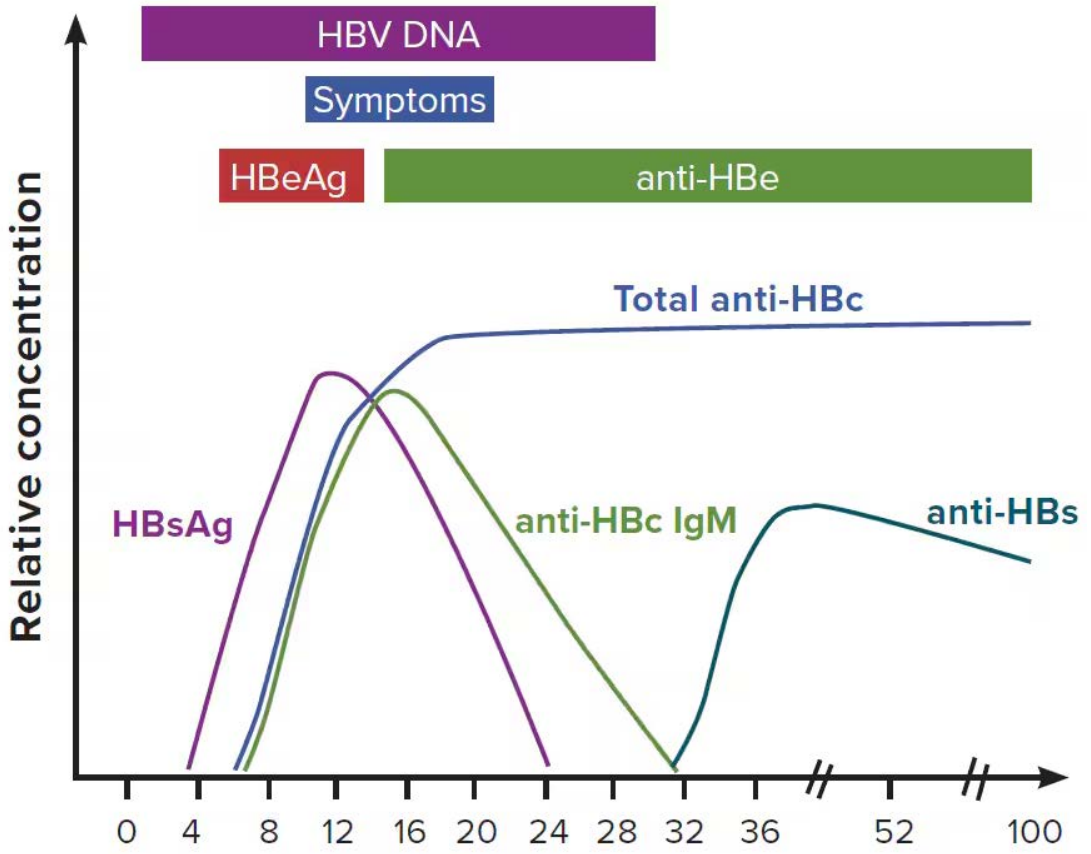


Figure 2.3. Acute HBV Infection with Recovery, Typical Serologic Course

The most common uses for testing are to determine whether a patient's signs and symptoms are due to HBV infection, to diagnose and monitor chronic infection, and to detect previous exposure to the virus. Testing may also be done to:

- screen for infection in at-risk populations or blood donors
- to determine carrier status
- screen for immunity due to vaccination or prior infection (See Table 2.2)

Factor to Be Tested	HBV Antigen or Antibody	Purpose
HBsAg	Hepatitis B surface antigen	Detection of acutely or chronically infected persons
Anti-HBs	Antibody to HBsAg	Identification of persons who have resolved infections with HBV; determination of immunity after immunization
Anti-HBc	Total Hepatitis B antibody	To determine a current or past Hepatitis B infection
HBeAg	Hepatitis B “e” antigen	Identification of infected persons at increased risk for transmitting HBV
HBV DNA	Hepatitis B DNA	HBV DNA measures the amount of HBV present. HBV DNA levels guide anti-viral therapy

Table 2.2. Diagnostic Tests for HBV Antigens and Antibodies, Quick Reference

Diagnostic Tests for HBV

Diagnosis of HBV infection (acute vs. chronic) is based on clinical, laboratory, and epidemiologic findings. HBV infection cannot be differentiated from other liver disease based on clinical symptoms alone, and definitive diagnosis depends on the results of laboratory testing. Serologic markers of HBV infection vary depending on whether the infection is acute, chronic, or resolved. Commercial tests for Hepatitis B, as summarized in Table 2.2, are widely available and used for various clinical purposes.

Refer to Chapter 5 for more detail on the diagnostic tests for HBV antigens and antibodies. Refer to Appendix D for comprehensive CDC resources on the interpretation of hepatitis B serology and information on assays not routinely required for the PHBPP.

Chapter 2 Learning Check

1. True or False: Chronic hepatitis B can lead to cirrhosis and liver cancer.

   Answer: True. Chronic Hepatitis B can lead to chronic hepatitis, cirrhosis, liver failure, and liver cancer. Worldwide, the most common risk factor for liver cancer is a chronic infection with Hepatitis B or Hepatitis C. The Hepatitis B vaccine was the first cancer preventing vaccine.

2. Hepatitis B virus is spread in the following ways:

   A. Breastfeeding
   B. Needle sticks
   C. During childbirth
   D. Both B and C

   Answer: D. Hepatitis B is spread through parenteral or mucosal exposure to HBsAg positive body fluids or tissues from those who have acute or chronic hepatitis B. Breast milk is thought to contain negligible amounts of hepatitis B and CDC and WHO state that it is safe for an infected mother to breastfeed their infant.

3. Which of the following clients should be screened, based on their risk factors?

   A. A recent immigrant from Nigeria
   B. A client who recently started dialysis
   C. A recent immigrant from Mexico
   D. Someone who reports a history of injection drug use
   E. A, B, and D

   Answer: E. Some risk factors for hepatitis B include people born in Asia, Africa, and other regions with moderate or high rates of hepatitis B; people on hemodialysis; and people who inject drugs. Mexico is not an area with high Hepatitis B infections per the CDC's yellow book.

Chapter 3: Texas Statutes and Rules

Reporting, Screening, and Vaccinating for Hepatitis B in Texas

The State of Texas provides legislative directives for hepatitis B screening and reporting to protect the residents of Texas from infectious disease. This chapter addresses statutes and rules that require providers to screen pregnant women for hepatitis B, administer vaccines to newborns and children, and report infected mothers and infants to the health department. The test currently recommended by the Centers for Disease Control and Prevention (CDC) for evaluation of hepatitis B infection during pregnancy is the Hepatitis B Surface Antigen (HBsAg). The Texas Department of State Health Services (DSHS) Immunization Section, Perinatal Hepatitis B Prevention Program (PHBPP) website, www.texasperinatalhepb.org**,** provides links to access statutes and rules pertaining to screening, reporting, and vaccinating newborns. Statutory requirements and rules must be shared with health care providers and labor and delivery facilities to reduce the incidence of transmission of perinatal hepatitis B.

Statutory Requirements - Texas Health and Safety Code

Chapter 81 Section §81.041 **– Reportable Diseases**

The Commissioner identifies each communicable disease or health condition that shall be reported. Each reportable disease is classified according to its nature and severity.

Chapter 81 Section §81.042 **– Persons Required to Report**

When a reportable disease is suspected, health professionals, and laboratories should report all known information of the case to the local health authority or DSHS.

Chapter 81 Section §81.044 **– Reporting Procedures**

The Commissioner shall prescribe the form and method of reporting which may be in writing, by telephone, by electronic data transmission, or by other means. The Commissioner may require reports to contain any information pertaining to a case that is necessary including, but not limited to:

- Patient's name, address, age, sex, race, and occupation
- Date of onset of disease or condition
- Probable source of infection
- Name of the attending physician.
- Please see Texas Administrative Code (TAC) Title 25, Chapter 97, Subchapter F Rule §97.3 (TAC Rule §97.3) referenced later in this chapter for additional reporting requirements.

Chapter 81 Section §81.090 **– Diagnostic Testing During Pregnancy and After Birth**

Providers that are permitted by law to care for a pregnant woman during gestation are required to perform hepatitis B serologic testing during pregnancy at the first prenatal visit. This report shall be retained for at least nine months and be reported to any successor in the case.

Providers that are permitted by law to care for pregnant women at delivery of an infant are required to perform hepatitis B serologic testing of the mother upon admission for delivery. Before testing a pregnant woman for hepatitis B, providers shall distribute to the patient printed materials about hepatitis B and subsequently document that the distribution of printed materials was made. The materials should inform the patient about the incidence and mode of transmission of hepatitis B and how being infected could affect the health of their child. Information shall also be provided or made available to the pregnant woman relating to the treatment of hepatitis B, which must be in another language if needed, and must be presented in a manner and in terms understandable to a person who may be illiterate, if resources permit. Physicians are complying when referring these individuals to an entity that provides treatment for individuals infected with hepatitis B.

Chapter 161 Section §161.004 **– Statewide Immunization of Children**

Every child in the state shall be immunized against vaccine-preventable diseases caused by infectious agents, in accordance with the immunization schedule adopted by DSHS.

Hospitals shall be responsible for:

- referring newborns for immunization at the time the newborn screening test is performed,
- reviewing the immunization history of every child admitted to the hospital or examined in the hospital's emergency room or outpatient clinic, and
- administering needed vaccinations or referring the child for immunization.

Physicians shall be responsible for reviewing the immunization history of every child examined and administering any needed vaccinations or referring the child for immunization.

A child is exempt from an immunization required by this section if either of the following apply:

- a parent, managing conservator, or guardian states that the immunization is being declined for reasons of conscience, including a religious belief, or
- the immunization is medically contraindicated based on the opinion of a physician licensed by any state in the US who has examined the child.

A parent, managing conservator, or guardian may choose the health care provider who administers the vaccine or immunizing agent under this chapter.

Rules - Texas Administrative Code

The TAC is a compilation of all state agency rules in Texas with specific rulemaking authority from the Legislature.

Title 25, Chapter 97, Subchapter A, Rule §97.2 **– Who Shall Report**

A physician, advanced practice nurse, physician assistant, or person permitted by law to attend to a pregnant woman during gestation or at the delivery of an infant shall report, as required, each patient who has or is suspected of having any notifiable condition. An employee from the clinical or office staff may be designated as the reporter and the provider must ensure that person regularly reports every occurrence.

Any person who is in charge of a clinic laboratory in which a laboratory examination of any human specimen yields serologic evidence of a notifiable condition shall report as required.

Failure to report a notifiable condition is a Class B misdemeanor under the Texas Health and Safety Code §81.049.

The Health Insurance Portability and Accountability Act (HIPAA) allows reporting without authorization for public health purposes and where required by law. See Title 45 Code of Federal Regulations §164.512 at the end of this chapter.

Title 25, Chapter 97, Subchapter F Rule §97.3 **– What Conditions to Report or Submit**

Hepatitis B (acute and chronic) identified prenatally or at delivery (mother) and hepatitis B acquired perinatally (child) are listed as notifiable conditions and must be reported.

The following information is listed as “minimal reportable information requirements” that shall be reported for hepatitis B (chronic and acute) identified prenatally or at delivery:

- Mother’s name, address, telephone number, age, date of birth, sex, race, ethnicity, and preferred language
- Hepatitis B laboratory results
- Estimated delivery date, or date and time of birth
- Name and phone number of delivery facility or planned delivery facility
- Name of infant
- Name, phone number, and address of medical provider for infant
- Date, time, formulation, dose, manufacturer, and lot number of Hepatitis B vaccine and Hepatitis B immune globulin (HBIG) administered to infant

The following information is listed as “minimal reportable information requirements” that shall be reported for perinatal hepatitis B infection:

- Name of infant, date of birth, sex, race, and ethnicity
- Name, phone number, and address of medical provider for infant
- Date, time, formulation, dose, manufacturer, and lot number of Hepatitis B vaccine and HBIG administered to infant, and any hepatitis B laboratory results*

*Refer to Chapter 4, Post-Exposure Prophylaxis (PEP), for chart of manufacturers and formulations of HBIG.

Title 25, Chapter 97, Subchapter A, Rule §97.4 **– When to Report a Condition**

Perinatal hepatitis B shall be reported within one working day of identification as a suspected case.

Hepatitis B (acute and chronic) identified prenatally or at delivery shall be made no later than one week after a case or suspected case is identified.

Title 25, Chapter 97, Subchapter A, Rule §97.5 **– Where to Report/Submit a Condition**

Physicians, hospitals, labs, and/or any person permitted by law to attend to a pregnant woman during gestation or delivery shall report to the Local Health Department (LHD) where the office, clinic, or hospital is located. If there is no LHD appointed for their jurisdiction, the report shall be made to the DSHS PHRPHR. Under 97.6, local health departments are required to report to DSHS any notifiable conditions report to them.

Title 25, Chapter 97, Subchapter A, Rule §97.8 **– General Control Measures for Notifiable Conditions**

Control techniques including immunization, chemoprophylaxis, and other accepted measures shall be instituted as necessary to reduce morbidity and mortality by the Commissioner, a health authority, or a duly authorized representative of the commissioner or a health authority. Information concerning [perinatal hepatitis B] and its prevention shall be given to the patient to prevent further spread of the disease. Investigation shall be made, as needed, for verifying the diagnosis, disclosing unreported cases, and finding contacts. On request, a person shall provide DSHS or health authority with records, data, and other information, which DSHS or the health authority will keep confidential.

Title 25, Chapter 97, Subchapter A, Rule §97.10 **– Confidential Nature of Case Reporting and Records**

All individual morbidity case reports received by the health authority or DSHS are considered confidential records. To implement disease control measures authorized in the TAC, it may be necessary for the health authority or the department to investigate public or private health records, including patient medical records pertinent to the notifiable condition. On request, a person shall provide the department with records, data, and other information according to the written instruction of the department. The health authority and the department shall keep this information confidential.

Title 25, Chapter 97, Subchapter D, Rule §97.101 **– Statewide Immunization of Children by Hospitals, Physicians, and Other Health Care Providers**

All private and public hospitals in Texas that provide health care to children shall administer age-appropriate vaccines or refer newborns for immunization to other health care providers at the time of the newborn screening test.

All physicians and other health providers who provide care to children shall review the immunization history of every child examined and administer vaccines or refer every child who needs immunizations to another provider.

Hospitals, physicians, and other health providers, who provide health care to children in Texas, must document in a newborn's or other child's hospital or medical record that the newborn or child has been age-appropriately immunized or that the newborn or child has been referred to another health care provider for immunizations. (Refer to Chapter 4 for Immunization Guidelines)

Federal Regulations - The Code of Federal Regulations (CFR)

Title 45, §164.512(b) **– Uses and Disclosures for Public Health Activities**

A covered entity may disclose protected health information to a public health authority authorized by law for activities to prevent or control disease such as surveillance, investigations, and interventions.

Sources

The Texas Health and Safety Code is available at:
http://www.statutes.legis.state.tx.us/?link=HS

The Texas Administrative Code is available at:
http://www.sos.state.tx.us/tac/index.shtml

The Code of Federal Regulations is available at:
https://www.govinfo.gov/app/collection/cfr/2023/

Chapter 4: Post-Exposure Prophylaxis (PEP)

Prevention

The Centers for Disease Control and Prevention (CDC) has released a comprehensive document pertaining to the elimination of Hepatitis B Virus (HBV) infection in the U.S. This document provides recommendations of the Advisory Committee on Immunization Practices (ACIP) and strategies to implement these recommendations in both children and adults. The primary focus of the ACIP childhood recommendations is the universal vaccination of infants as a "safety net" to prevent early childhood HBV infection.

The strategies to prevent hepatitis B infection in children include, but are not limited to:

- Universal vaccination of infants beginning at birth
- Routine screening of all pregnant women for Hepatitis B Surface Antigen (HBsAg)
- PEP of infants born to HBsAg-positive women or to women with unknown HBsAg status
- Routine vaccination of previously unvaccinated children and adolescents

In this document, the CDC also provides strategies to enhance implementation of the ACIP recommendations, such as:

- Establishing standing orders for administration of hepatitis B vaccination at birth; and
- Implementing policies and procedures to improve identification of, and administration of PEP to, infants born to:
    - mothers who are HBsAg positive, and
    - mothers with unknown HBsAg status at the time of delivery.

The CDC and ACIP recommend that providers who practice in primary care and at-risk specialty settings should implement standing orders to identify their at-risk patients and subsequently vaccinate them. The document can be accessed electronically at: https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm The Institute of Medicine (IOM) (now called National Academy of Medicine [NAM]) also released a report on preventing and controlling viral hepatitis infections in the U.S. After reviewing evidence on the prevention and control of hepatitis B and hepatitis C, the committee identified the underlying factors that impeded current efforts to prevent and control these diseases. In this report, ***Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C,*** the committee offers recommendations in four categories: surveillance, knowledge and awareness, immunization, and services for viral hepatitis. This document, along with recommendations from ACIP can be found at the following web site: http://www.cdc.gov/hepatitis/pdfs/iomhepatitisandlivercancerreport.pdf**.**

Post-Exposure Prophylaxis (PEP)

Hepatitis B Immune Globulin (HBIG)

HBIG is derived from human plasma. The plasma, which is processed from select human donors with high Hepatitis B Surface Antibody (anti-HBs) titers, contains antibodies that are specific to the hepatitis B virus. Although HBIG is derived from humans, it is purified to prevent passing along disease to the person who receives it. HBIG is used to give temporary protection for individuals who might have been exposed to the virus. It is important to keep in mind that immune globulin does not provide long-term protection in the same way that vaccinations do. The protection is only short term, usually only lasting a few weeks to a few months. In the case of perinatal hepatitis B, HBIG is intended to give infants born to mothers with hepatitis B short-term protection against the hepatitis B virus, which they may have been exposed to during birth.

Infants born to HBsAg-positive women should receive HBIG and the birth dose of hepatitis B vaccine within 12 hours of birth. See Table 4.1 for HBIG products and basic administration information. By the time effectiveness of the HBIG dose has waned, the infant's immune system should be producing its own anti-HBs antibodies to the hepatitis B virus in response to the vaccine. It is important that the infant complete the vaccine series on time to give them the best chance of developing immunity against the virus. See Table 4.2 for indications for HBIG use, based on the infant's birth weight and mother's testing results.

Product Name	Manufacturer	Perinatal Dosing	Presentation*
HepaGamB	Cangene Corporation	0.5 mL	1.0 mL single use vial
HyperHEPB	Grifols	0.5 mL	0.5 mL single dose syringe
Nabi-HB	Biotest Pharmaceuticals	0.5 mL	1 mL single dose vial

**As relevant only to perinatal administration*

Table 4.1 HBIG Product Dosing Information for Perinatal Exposure

Hepatitis B Vaccine

The hepatitis B vaccine is the best protection against HBV infection. In 1986, research led to a recombinant hepatitis B vaccine that was synthetically modified and did not contain any blood products. It was later licensed for use in the U.S. in 1989. This was the first vaccine licensed in the country that was produced by recombinant DNA technology. HBV infection cannot result from use of the recombinant vaccine, since no potentially infectious viral DNA or complete viral particles are produced in the recombinant system.

The hepatitis B vaccine is available as both a single-antigen formulation (monovalent vaccine) and in a fixed combination with other vaccines (combination vaccine). As of March 2000, all hepatitis B vaccines produced for distribution in the U.S. are thimerosal-free. See Table 4.2 for administration recommendations, based on the infant's birth weight and mother's testing results.

Infants weighing 2,000 g or more (4.4 lbs. or more) born to	
HBsAg-positive mother	
HBIG	Administer within 12 hours
Hepatitis B birth dose	Administer within 12 hours
HBsAg-unknown mother	
HBIG	If positive results are received, administer HBIG immediately.
	Administer HBIG prior to discharge or within seven days, whichever is sooner. HBIG must be administered within seven days of birth.
	If negative results are received before discharge, no HBIG needed.
Hepatitis B birth dose	Administer within 12 hours
HBsAg-negative mother	
HBIG	No HBIG needed
Hepatitis B birth dose	Administer within 24 hours
Infants weighing less than 2,000 grams (less than 4.4 pounds) born to	
HBsAg-positive mother	
HBIG	Administer within 12 hours
Hepatitis B birth dose	Administer within 12 hours
HBsAg-unknown mother	
HBIG	Administer within 12 hours
Hepatitis B birth dose	Administer within 12 hours
HBsAg-negative mothers	
HBIG	No HBIG needed
Hepatitis B birth dose	Provider may defer to be given at one month of age, or at discharge if infant is released before one month

Table 4.2 Post-Exposure Prophylaxis (PEP) for Infants at Birth

Importance Of The Hepatitis B Vaccine Birth Dose

Hepatitis B vaccine was first recommended for administration to all infants in 1991 by the ACIP as the primary focus of a strategy to eliminate HBV transmission in the United States. The recommended timing of administration of the first dose of hepatitis B vaccine to infants has evolved since then to optimize prevention of perinatal and early childhood HBV infections. In 1991, the first dose was recommended to be administered at birth before hospital discharge or at age one to two months. This recommendation helped dramatically decrease the number of new hepatitis B infections among children in the U.S. One study found a 68% decrease in perinatal hepatitis B infections within ten years of initiation of the universal birth dose. In January 2018, ACIP published recommendations to give the first dose of hepatitis B vaccine within 24 hours of birth for all stable newborns who weigh 2,000 grams or more (4.4 pounds or more).

The CDC recommends that all infants born to HBsAg positive mothers, or mothers whose status is unknown, should receive the birth dose of hepatitis B vaccine at birth, regardless of birth weight. All infants weighing less than 2,000 grams (less than 4.4 pounds) at birth and who received the birth dose of hepatitis B vaccine should have the series reinitiated at one month of age or older. The birth dose should not be considered a valid dose as part of the series in these infants. These infants will receive between four and five doses of hepatitis B vaccine, depending on the formulation of vaccine used after the birth dose.

Exceptions to the universal birth dose should be rare and considered on a case-by-case basis. Any health care provider who decides to delay the birth dose must document the order to do so and ensure that a copy of the mother's laboratory report, indicating she was HBsAg-negative during this pregnancy and at delivery, is present in the infant's medical record. The birth dose should not be delayed in infants whose mother tested HBsAg-positive prenatally and/or at delivery.

The hepatitis B vaccine birth dose serves as a "safety net" if a mother was misdiagnosed as HBsAg-negative prenatally and/or at delivery. Children born to HBsAg-positive mothers who do not become infected during the perinatal period remain at high-risk of infection during early childhood. In one study, 40% of infants who were not infected perinatally became infected by the age of five years old. Guidelines for standing orders in labor and delivery and nursery units to prevent hepatitis B virus transmission to newborns can be found in Appendix E of this manual and on the DSHS Immunization Section PHBPP website at www.texasperinatalhepb.org.

Immunization Action Coalition (IAC) Birth Dose Honor Roll

The universal birth dose policy is imperative as a safety net for infants who could be at risk for HBV. The Immunization Action Coalition (IAC) recognizes birthing facilities/hospitals that have reached high coverage rates of the Hepatitis B Birth Dose. These facilities are awarded and enrolled in the Hepatitis B Birth Dose Honor Roll. This impressive designation demonstrates the hospital's commitment to preventing HBV transmission.

To qualify for the Hepatitis B Birth Dose Honor Roll, a birthing facility/hospital needs to demonstrate that they achieved a rate of 90% or higher for administering the hepatitis B vaccine dose before hospital discharge to all newborns during a 12-month period. In addition, the facility/hospital needs to have written policies and procedures to ensure that all newborns are protected from HBV infection before hospital discharge.

Examples of policies include, but are not limited to:

- Ensuring all parents are informed about the importance of the hepatitis B vaccine birth dose
- Ensuring all newborns routinely receive the hepatitis B vaccine after birth and before discharge
- Reviews of charts to ensure the correct screening test, HBsAg, was ordered for mothers during their current pregnancy
- Results of all mothers' HBsAg testing are reviewed
- Ensuring all infants born to HBsAg-positive mothers receive HBIG and hepatitis B vaccine within 12 hours of birth
- Implementing routine newborn admission orders that include a standing delegation order (SDO) to administer hepatitis B vaccine to all newborns
- Ensuring all mothers with a positive HBsAg are reported to the Local Health Department (LHD) prior to discharge

Texas has the highest number of birth dose honor roll enrollees in the nation.
Many of these facilities/hospitals have also qualified for more than a one-time period.
This notable achievement demonstrates the outstanding efforts of the state's birthing facilities/hospitals and perinatal hepatitis B case managers as they strive to improve health for all Texans.

For more information about the Hepatitis B Birth Dose Honor Roll and how to apply, visit: www.immunize.org/honor-roll/birthdose/.

For the most current list of all the hospitals enrolled, visit:
https://www.immunize.org/about/excellence/honor-rolls/hepb-birth-dose/.

Vaccination Schedule and Use

Infants And Children

Hepatitis B vaccination is recommended for nearly all infants within 12–24 hours of birth.
Common formulations of the vaccine and their administration are:

Engerix B® (GlaxoSmithKline)

- 0.5 mL (10 mcg)/dose
- Approved: 19 years old and younger
- Three doses – administered Intramuscularly (IM)
- Schedule: Birth, One-two months, six months

Recombivax HB® (Merck)

- 0.5 mL (5 mcg) / dose
- Approved: 19 years old and younger
- Three doses – administered IM
- Schedule: Birth, one-two months, six months

Pediarix® (GlaxoSmithKline): DTaP+Hep B+IPV

- 0.5 mL (10mcg)/dose
- Approved: six weeks – six years of age
- Three doses* – administered IM
- Schedule: two, four, six months
- Should not be used for the birth dose

  * It is important to note that although Pediarix® is approved as a three-dose series, children who receive Pediarix® on the appropriate schedule will receive four doses of the Hepatitis B vaccine, including the birth dose. This is safe and will not harm the child.

It is preferred that the same vaccine/manufacturer be used for completion of a series. The FDA licenses combination vaccines based on their efficacy and safety when compared to monovalent vaccines. If the vaccine the child previously received is not immediately available, or is unknown, vaccination should not be delayed; the child should receive the available age-appropriate vaccine.

Infants should not receive the final dose of hepatitis B vaccine prior to six months of age. If the third dose is inadvertently given before six months (24 weeks) of age, the dose should be repeated and administered once the child is at least 24 weeks of age. Because the highest anti-HBs are achieved when the last two doses of vaccine are spaced at least four months apart, schedules that achieve this spacing are preferable. However, schedules with two-month intervals between doses (i.e., Pediarix®), which conform to schedules for other childhood vaccines, have been shown to produce good antibody responses and may be appropriate in populations where it is difficult to ensure that infants will be brought back for all their vaccinations. The minimum intervals for the hepatitis B vaccine schedule to produce a good antibody response in infants are as follows:

- The second dose should be administered at least four weeks after the first dose.
- The third dose should be administered at least eight weeks after the second dose.
- The third dose should be administered at least 16 weeks after the first dose.
- The third dose should not be administered any earlier than 24 weeks of age (6 months).

It is not necessary to add doses or restart the series if the interval between doses is longer than recommended. Doses administered too soon (before the minimum intervals noted above), should be re-administered using the correct interval. The minimum interval that should be used when a dose is administered too soon should be calculated from the incorrectly administered dose. For example, children who incorrectly received their third dose of the hepatitis B vaccine at age five months, should not receive the correct final dose until eight weeks after the wrong dose was given, meaning the child should not receive the correct/final dose until age seven months.

Three doses of the hepatitis B vaccine are required for students in Kindergarten-12th grade. Hepatitis B vaccine is also required for children to attend licensed childcare facilities. One dose for children three to four months, two doses for children five to 15 months, and three doses for all children 16 months of age or older.

Pre-term And Low Birth Weight Infants

Pre-term infants born to HBsAg-positive women and women with unknown HBsAg status must receive PEP with the hepatitis B vaccine and HBIG within 12 hours of birth.

Pre-term infants and those with low birth weight (less than 2,000 grams or less than 4.4 pounds) have a decreased response to the hepatitis B vaccine when administered before one month of age. However, by one month of age, pre-term infants, regardless of initial birth weight or gestational age, are likely to respond as adequately as full-term infants. Therefore, pre-term infants or those born weighing less than 2,000 grams (less than 4.4 pounds) should restart the hepatitis B vaccine series at one month of age. Since the birth dose does not count toward completion of the hepatitis B series for these infants, they need to receive a total of at least four doses of the hepatitis B vaccine. Although the birth dose is not considered a valid dose in the series for these infants, it is imperative that any infants born to mothers with either HBsAg-positive or HBsAg-unknown status receive the birth dose, in addition to HBIG, for the best protection.

If ordered by the physician, pre-term or low birth weight infants whose mothers tested as HBsAg-negative during this pregnancy and at delivery can defer the first dose of the hepatitis B vaccine series to one month of age. In this case, both of the mother's negative lab reports must be documented in the infant's chart by the ordering physician.

These infants, if discharged from the hospital before one month of age, can also receive the hepatitis B vaccine at discharge if they are medically stable and have gained weight consistently. The full recommended dose should be used. Divided or reduced doses are not recommended.

Vaccine Administration And Contraindications

The hepatitis B vaccine can be given concurrently with other vaccines. Pregnancy and lactation are not contraindications to receiving a hepatitis B vaccination. The vaccine is to be administered intramuscularly (IM) in the anterolateral thigh or deltoid area, depending on age of the recipient. The choice of site is based on the volume of the injected material and the size of the muscle. In children younger than three years of age, the anterolateral aspect of the thigh provides the largest muscle and is the preferred site; the deltoid muscle can be used in children older than 12 months of age if the muscle mass is adequate. In children three years and older, the deltoid muscle is usually large enough for IM injection. The upper, outer aspect of the buttocks should never be used for vaccine administration because of diminished immunogenicity and the possibility of damaging the sciatic nerve.

Adverse Reactions

The most common adverse reaction associated with the hepatitis B vaccine administration is pain at the injection site. Less frequent adverse reactions include fatigue, headache, irritability, and a fever greater than 99.9°F. There is no scientific data or evidence to show an association between the hepatitis B vaccine and sudden infant death syndrome (SIDS), multiple sclerosis (MS), autoimmune diseases, chronic fatigue syndrome, or autism.

Post-vaccination Serologic Testing (PVST)

Post-vaccination seroprotection is achieved in 98% of healthy full-term infants who received a three or four series HBV dose series; infants of low birthweight (less than 2,000 grams/less than 4.4 pounds) will generally have a lower seroprotection. Because not all infants will adequately respond to the hepatitis B vaccine series, it is important that all infants born to HBsAg-positive mothers, or mothers whose HBsAg status cannot be determined (e.g., safe surrender), be tested for vaccine response after completion of the series. This will ensure that an adequate immune response is reached.

Testing for immunity following hepatitis B vaccination is routinely recommended by the CDC for at-risk infants who are born to HBsAg-positive women or women whose hepatitis B status remains unknown. The guidance on timing of post-vaccination serologic testing (PVST) provided by the CDC indicates that the optimal time to collect PVST in infants who completed the vaccine series on time is at nine to twelve months of age. For infants whose series was delayed, the PVST should be collected one to two months after completion of the series.
NOTE: Testing is not recommended before nine months to avoid possible detection of anti-HBs passively transferred from the mother or from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection. It is important to test for HBsAg and anti-HBs to determine the success or failure of vaccination. It is important to keep in mind that testing delays after series completion can lead to false negative anti-HBs results.

Infants who completed the vaccine series on time at six months of age, should have PVST performed three months after the final dose of the hepatitis B vaccine series has been administered to determine the success of PEP. This would ideally occur at the next well-child visit at nine months of age.

Infants who were delayed or delinquent in completing the vaccine series should receive the PVST one to two months after completion, as long as the infant is nine months of age or older. For example, an infant who did not receive their final dose of the hepatitis B vaccine until eight months of age can still complete the PVST on time at nine months of age, so long as at least 28 days has passed since the last vaccination.

NOTE: Testing delays after series completion can lead to false-negative anti-HBs results.
Providers should not order a hepatitis panel when performing PVST, as it typically does not include testing for immunity, but rather only screens for acute hepatitis infection.
Providers should order the individual serology markers, HBsAg and anti-HBs. Refer to Chapter 5 for additional information on specific serology markers and their interpretation.

Procedures For Ordering HBIG And Hepatitis B Vaccine

The HBIG and hepatitis B vaccine are costly and delicate biological products.
Keeping a large inventory increases the risk for expiration. Review the expiration dates on the vaccines received and use the shortest-dated vaccines first.

Hospitals, pediatricians, and other medical providers may order HBIG and the hepatitis B vaccine directly from the manufacturer. Providers should contact the manufacturer for ordering instructions.

DSHS PHRs and LHDs must ensure in advance that the hospital has HBIG on hand when a positive HBsAg woman is planning to deliver at the facility to ensure administration of HBIG and hepatitis B vaccine birth dose to the infant within 12 hours of delivery. HBIG can be ordered by PHRs or LHDs from the DSHS Immunization Section on an emergency basis. See below for Ordering Instructions. The LHDs must order HBIG and hepatitis B vaccine through their DSHS PHR. Both biologics must be shipped to a DSHS PHR or LHD location.

HBIG And Hepatitis B Vaccine Ordering Instructions From DSHS:

To order HBIG and hepatitis B vaccine for newborns, DSHS PHRs and LHDs must email the Texas Perinatal Hepatitis B Prevention Program (PHBPP) at TxPeriHepB@dshs.texas.gov **with the following information:**

- **The Provider Identification Number** (PIN)
- **Clinic Days and Hours:** List the hours the clinic will be open to accept vaccine shipments for each day of the work week and note lunch period when no one is available to receive the vaccine. Be sure to note any holidays or clinic closings.
- **Contact Person:** Name of person that is physically present at the clinic to accept the shipment.
- **Phone:** Phone number of the contact person.
- **Clinic Address:** Provide complete name and address of clinic.
- **Pick from List:** Provide the vaccine needed and the vaccine formulation requested and the request for HBIG.
- **Order Amount:** Indicate number of doses needed.
- **Date of Order:** Date the order was completed.

Upon receiving a vaccine request, the DSHS PHBPP will forward the request to the Vaccine Management Group to submit the order in the Inventory Tracking Electronic Assets Management System (ITEAMS).

The order will be shipped via the DSHS Pharmacy Unit. The DSHS Pharmacy Unit ships orders on Monday, Tuesday, and Wednesday of each week. To meet shipping deadlines, please submit all order request to TxPeriHepB@dshs.texas.gov. Orders must be received before 2:00 p.m. on these days.
Call the DSHS PeriHepB central office staff at 512-776-6035 in the event of an emergency.

Handling and Storage

Careful handling of hepatitis B vaccine and HBIG is extremely important. These procedures should be strictly followed:

- Transport only in insulated boxes with coolant to maintain proper temperature.
- Store biologics at 2-8°C (35-46°F). Do not freeze. Freezing destroys the potency of these biologics.
- Special care should be taken to avoid waste because of the high cost of the biologics. If biologics on hand are provided to your clinic by the Texas Vaccines for Children Program (TVFC) and are due to expire within 90 days, please contact your DSHS PHR or LHD for assistance in transferring the product.

Be sure to also refer to the package inserts for additional detailed storage and handling procedures.

If your vaccine is provided by the Texas Vaccines for Children (TVFC) program, be sure to follow all TVFC Program requirements. For more information on TVFC Program Requirements and Vaccine Storage and Handling, please visit: www.dshs.texas.gov/immunizations/providers/materials.

Chapter 4: Learning Check

1. True or False: HBIG needs to be given to infants born to HBsAg-positive women within 12 hours of birth because they are too young for the Hepatitis B vaccine.

   Answer: False. Both HBIG and the hepatitis B vaccine are given within 12 hours of birth in this case to help prevent perinatal HBV transmission. HBIG provides short-term protection against HBV that the infant may have been exposed to during birth. Because HBIG does not provide long-term protection, the infant must also receive the hepatitis B vaccine at birth and complete the vaccine series by six months of age.

2. Infants born to HBsAg-negative mothers should receive the Hepatitis B birth dose vaccine...

   A. Before hospital discharge
   B. At one month of age at their pediatrician's office
   C. Within 24 hours of birth
   D. Only if requested by the parents

   Answer: C. The current CDC recommendation is to give the birth dose of the hepatitis B vaccine to all stable infants (weighing 2,000 grams or more/4.4 pounds or more) within 24 hours of birth. All infants meeting the minimum weight should receive a birth dose, regardless of the mother's HBsAg status.

3. You are reviewing the vaccine history for an infant born to a HBsAg-positive woman and find that the infant has received the following vaccines:

   - Birth: Energix-B®
   - Two Months: Pediarix®
   - Four Months: Pediarix®
   - Six Months: Pediarix®

   How do you interpret this vaccine history?

   A. The infant has completed the Hepatitis B vaccine series.
   B. The infant received an extra dose of Hepatitis B vaccine and there is a vaccine error.
   C. The infant should repeat the Hepatitis B vaccine series since a different formulation was given after birth.

   Answer: A. The infant has completed the Hepatitis B vaccine series. No additional doses are needed and, although infants who receive Pediarix® on the appropriate schedule will get four total doses of the Hepatitis B vaccine; this is considered safe and is not a vaccine error.

Chapter 5: Serology Testing and Reporting

Diagnostic Tests for Hepatitis B Virus

Diagnosis of hepatitis B virus (HBV) infection, acute vs. chronic, is based on clinical, laboratory, and epidemiological findings. HBV infection cannot be differentiated from types of viral hepatitis from clinical symptoms alone, and definitive diagnosis depends on the results of laboratory testing. Serologic markers of HBV infection vary depending on whether the infection is acute, chronic, or resolved. Commercial tests for hepatitis B, as summarized in Table 5.1, are widely available and are used for various clinical purposes:

Hepatitis B Surface Antigen (HBsAg) is the most used test for HBV screening for infection. However, it does not differentiate between an acute and a chronic infection. HBsAg can be detected between one and 12 weeks after exposure to HBV. The presence of HBsAg indicates that a person is infectious, regardless of whether the HBV infection is acute or chronic. If the infection is self-limited (an acute infection), HBsAg disappears in most patients within a few weeks to several months after infection. People with chronic HBV infection continue to have circulating HBsAg.

Hepatitis B Surface Antibody (anti-HBs) is a protective, neutralizing antibody. The presence of anti-HBs following acute HBV infection generally indicates recovery and immunity against reinfection. Anti-HBs can also be acquired as an immune response to hepatitis B vaccine or passively transferred temporarily by administration of HBIG.

Total Hepatitis B Core Antibody (anti-HBc): The presence of this marker indicates a current or past infection with hepatitis B. It is recommended that this test be ordered with HBsAg and Anti-HBs to determine if an individual has an ongoing or previous infection with hepatitis B.

Hepatitis B "little e" Antigen (HBeAg) is a marker associated with HBV infection and, when present, indicates active viral replication within the liver, higher concentrations of HBV, and high infectivity. Testing for HBeAg is useful in identifying candidates for antiviral therapy and to monitor therapy response.

IgM Antibody to Hepatitis B Core Antigen (IgM anti-HBc): The presence of this marker indicates a new hepatitis B infection (within the last six months). A positive result indicates an acute infection.

Hepatitis B DNA (HBV DNA): HBV DNA is one of the first tests that can detect HBV in the bloodstream after initial infection. It can be detected as early as one week after infection. The amount of HBV DNA in the patient's blood indicates how fast the virus is replicating within the liver. This test measures the patient's viral load, or how much virus is present in the patient. High viral loads indicate rapid viral replication while low or undetectable levels indicate inactive infections. The Centers for Disease Control and Prevention (CDC) recommends all HBsAg positive pregnant women be tested for HBV DNA to guide antiviral therapy as needed.

Refer to Appendix D for additional CDC resources on ordering and interpreting hepatitis B serology.

Factor	HBV Antigen or Antibody	Purpose	CPT Code
HBsAg	Hepatitis B surface antigen	Detection of acutely or chronically infected persons.	87340 Confirmatory test: 87341
Anti-HBs	Antibody to HBsAg	Identification of persons who have resolved infections with HBV; determination of immunity after immunization	Quantitative (preferred): 86317 Qualitative: 86706
Anti-HBc	Total Hepatitis B antibody	To determine a current or past Hepatitis B infection	86704
HBeAg	Hepatitis B e antigen	Identification of infected persons at increased risk for transmitting HBV	87350
HBV DNA	Hepatitis B DNA	HBV DNA measures the amount of HBV present. HBV DNA levels guide anti-viral therapy.	87517

Table 5.1 Quick Reference for Ordering HBV Diagnostic Testing

Maternal Screening

According to Chapter 81, §81.090 of the Texas Health and Safety Code, providers who care for pregnant women are required to perform screening for hepatitis B at the first prenatal visit and at delivery. Providers should not select a viral hepatitis serology panel for testing; instead, they should select and order the individual hepatitis B serology markers. The serology markers are HBsAg, anti-HBs, and anti-HBc. The CDC also recommends providers order an HBV DNA test for any pregnant woman who has a positive HBsAg result.

HBsAg screening should occur when other routine prenatal testing is done. The HBsAg test is widely available and can be added to the routine prenatal panel of tests without requiring additional patient visits. The advantages of routine HBsAg testing at the first prenatal visit are:

- determining early in the pregnancy if the mother is HBsAg-positive so HBV carrier status can be better established at the time of delivery
- determining HBV DNA viral load early in the pregnancy to guide antiviral therapy as needed
- ensuring that the infant receives appropriate and timely Post-Exposure Prophylaxis (PEP) immediately after birth
- providing appropriate counseling to families before delivery
- obtaining the name of contacts less than 24 months of age for case management
- referral of household contacts less than 24 months of age and sexual partner(s) to a health care provider for evaluation of susceptibility, vaccination status, and/or HBV infection

Hepatitis B identified prenatally and/or at time of delivery is a reportable condition in Texas, as outlined in Chapter §81.041 of the Texas Health and Safety Code within one week of identification. All women identified as being HBsAg-positive while pregnant or at the time of delivery must be reported to their local or regional health department.

Investigational Form

If maternal screening was not performed during pregnancy and/or at delivery, documentation of the reason(s) as to why the mother was not screened should be stated on the “Investigational Report” form. Specific training regarding the identified issues in lack of screening should be provided to the provider/delivery hospital by the DSHS PHR or LHD office within 30 days.

Medical Records

Maternal HBsAg results, along with dates of testing, should be documented in all infant medical records. If HBsAg testing was not done prenatally or at delivery, it is the responsibility of the hospital and obstetrical care provider to ensure that the test is done before hospital discharge. If HBsAg results are positive, the hospital and obstetrical care provider are also responsible for administering the appropriate PEP to the infant in addition to reporting the positive result to the LHD as soon as possible, but no later than one week after results are obtained.

Standing Delegation Orders (SDOs)

Hospitals should develop written policies to ensure screening of all pregnant women and administration of PEP to all at-risk neonates. These policies should be assessed by the DSHS PHR and LHD each time the hospital receives training from the Perinatal Hepatitis B Prevention Program (PHBPP) case manager and any time there is a gap in HBsAg screening or PEP. These policies should include standing orders for the following key elements:

- Review prenatal HBsAg results of all pregnant women
- Test all mothers for HBsAg at each delivery
- Provide the first dose of the hepatitis B vaccine to all infants weighing 2,000 grams or more (4.4 pounds or more) at birth:
  - within 12 hours of birth for HBsAg positive mothers or mothers with unknown status, or
  - within 24 hours of birth, regardless of mother's HBsAg status.
- Provide appropriate PEP* (HBIG and birth dose of the hepatitis B vaccine) to all infants of HBsAg-positive mothers (prenatally and/or at delivery)
- If the mother's HBsAg status is unknown at the time of delivery, the mother's blood should be drawn as soon as possible to determine her HBsAg status. If positive, the infant should receive HBIG as soon as possible, but no later than seven days after birth* and
- Report all HBsAg-positive mothers to the DSHS PHR or LHD within one week of identification.

* For additional guidance on PEP of infants born to women who are HBsAg-positive or HBsAg-unknown status, please refer to Chapter 4 of this manual.

Serologic Testing of Infants and Children

Pre-vaccination Serologic Testing

Serologic testing is not recommended before routine vaccination of infants and children, nor is it recommended for infants born to HBsAg-positive women immediately after birth. ***See guidelines and recommendations below for the appropriate timing of serology testing of at-risk infants.***

Serologic Testing for Immunity of Infants and Contacts 24 Months of Age and Younger

Testing for immunity following vaccination is routinely recommended for infants who are born to HBsAg-positive women. These infants should complete PVST and be tested for infection (HBsAg) and immunity (Anti-HBs). The CDC's recommendations and general guidance for PVST can be found in the January 12, 2018 Morbidity and Mortality Weekly Report (MMWR) titled ***Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices***, accessible at https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm.

The MMWR states that PVST should be done one to two months after completion of the vaccine series. However, testing is not recommended before age nine months to avoid possible detection of anti-HBs from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection. Therefore, infants who received their final dose of hepatitis B vaccine at six months of age must wait three months for PVST to be done; ideally at the next well-child visit at nine months to determine the success of PEP. It is important to test for both HBsAg and anti-HBs to determine the success or failure of vaccination, as up to five percent of infants may not respond adequately to vaccination.

NOTE: Testing delays after series completion can lead to false-negative anti-HBs results. Providers should order the individual serology markers HBsAg and anti-HBs.

NOTE: Providers should not order a hepatitis panel when performing PVST, as it typically does not include testing for immunity, but rather only screens for acute hepatitis infection. Most commercial labs can add additional lab testing to existing specimens within a few days of specimen collection. Case managers can prevent additional lab draws by verifying serology orders within a few days of specimen collection and adding appropriate serology markers as needed.

NOTE: For contacts 24 months of age or younger, the same serologic testing (HBsAg and anti-HBs) should be done, at least one month after the final dose of the hepatitis B vaccine series is completed, and if the child is at least nine months of age.

Post-Vaccination Serologic Testing Interpretation

Test Results	Interpretation	Action
HBsAg (-) **Anti-HBs (+)**	Immune due to vaccination	1. Notify the DSHS PHR or LHD 2. No additional action needed
HBsAg (-) **Anti-HBs (-)**	Susceptible / Non-responder	1. See guidance below 2. Notify the DSHS PHR or LHD
HBsAg (+) **Anti-HBs (-)**	Infant infected with Hepatitis B Virus	1. Notify the DSHS PHR or LHD 2. Provide education/counseling 3. Refer for evaluation

Table 5.3 Response to Infant Serologic Test Results

Susceptible/Non-responder

The CDC recently updated its guidelines for at-risk infants who do not respond to the first hepatitis B vaccine series. Children that fail to respond to the first complete hepatitis B vaccine series need to receive a single dose of hepatitis B vaccine immediately and have PVST repeated one to two months later. Infants who have repeat anti-HBs less than 10 mIU/mL should receive the next two vaccines in the series, followed by PVST one-two months after the final dose. Alternatively, providers and families may skip the booster dose of hepatitis B vaccine and repeat the entire three-dose vaccine series, followed by repeat PVST one-two months later. Single-dose revaccination has many advantages, including fewer vaccine doses, shorter duration of case management, and lower cost. Please see the January 12, 2018, MMWR titled ***Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices***, accessible at https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm, for more details.

Note that children who fail to respond to two complete series of the hepatitis B vaccine are considered non-responders and parents/guardians should be counseled regarding susceptibility and prevention of virus transmission.

Serologic Testing for Immunity on Contacts older than 24 Months of Age

Services are not provided through the PHBPP for contacts older than 24 months of age.
These contacts should be referred to a provider for health care evaluation. Document the referral on the mother's case management form.

Serologic Testing of Mothers with unknown HBsAg status

Prenatal HBsAg Status	Delivery HBsAg Status	Action
Unknown	Unknown	Test for HBsAg immediately
Positive	Unknown	
Unknown	Positive	In six months, patient should be referred for the following tests: HBsAg, anti-HBs, and anti-HBc.

Table 5.4 Testing Response to Mothers' Serologic Test Status

Should the patient not have health insurance (or their health insurance is refusing to pay), serology testing for HBsAg, anti-HBs, and anti-HBc is provided by DSHS at no cost to the client.
If the mother's HBsAg status is unknown at delivery, the mother, her infant, and contacts less than or equal to 24 months of age must receive appropriate case management until the mother's status is determined. If determined to be positive, case management services shall be continued until completion of the program. Contacts greater than 24 months of age should be referred to a health care provider for testing and vaccination if susceptible. Additionally, the new MMWR states that PVST should be completed for any infants whose mother's HBsAg status remains unknown indefinitely (e.g., infants who are safely surrendered after birth).

Discrepant HBsAg Results

Discrepant results occur when the mother's HBsAg tests during the current pregnancy yield conflicting results.

	Prenatally	At Delivery	Hospitals
HBsAg Test Results	Positive (+)	Negative (-)	• Administer HBIG and hepatitis B vaccine-birth dose within 12 hours of birth • Report case to DSHS PHR or LHD
	Negative (-)	Positive (+)	

Table 5.4 Hospital Response at Delivery to Mothers' Discrepant Serologic Test Status

All infants born to mothers with discrepancies in their HBsAg test results should receive HBIG and Hepatitis B vaccine within 12 hours of birth. It is the role of the delivery hospital to administer appropriate PEP within 12 hours of birth to all infants born to mothers with discrepant HBsAg results and to report results to the DSHS PHR or LHD. Refer to Chapter 4 for further guidelines on PEP.

Any positive HBsAg result should undergo confirmation by neutralization. If the sample is confirmed, the result is considered positive for HBsAg. If the sample is negative upon confirmation, then the HBsAg is considered negative even though the preliminary result was positive.

It is necessary to gather more information when there are discrepant HBsAg results during the pregnancy. First, verify that the HBsAg positive result was confirmed by neutralization. Also, determine if the client had any prior testing or has received hepatitis B vaccines. Additionally, it is helpful to have providers order HBsAg, Anti-HBs, and Anti-HBc to help determine Hepatitis B status.

The Role of the DSHS PHR and LHD

PHR and LHD The LHDs must upload and enter the mother's discrepant HBsAg results directly to https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/within one week of notification. Create a mother's record, if not already within Salesforce and then create a mother's form.

Create a mother's record, if not already within Salesforce and then create a mother's form.

- Name
- Date of birth (DOB)
- Country of birth information
- Type(s) of tests
- Laboratories that performed the tests
- Hepatitis B vaccination dates (if applicable)
- Type(s) of vaccines (if applicable)
- Other pertinent health information

NOTE: Cases can be created at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/ Case managers should not delay submitting cases due to limited information or while waiting to interview the client. All case management information will be entered within Salesforce.

Case Management of Discrepant Hepatitis B serology results

Case managers should ensure that six months have passed between HBsAg-positive results to determine the mother's status. Repeat testing should include HBsAg, Anti-HBs, and Anti-HBc to help determine status.

Note that all cases should remain open, and follow-up of the infant and contacts 24 months of age or younger should be continued, until the mother's status can be determined.

Hepatitis B Immunity Laboratory Parameters

A positive anti-HBs of 10 mIU/mL or more indicates adequate immunity to hepatitis B.
This immunity may be from either a past hepatitis B infection or a hepatitis B vaccination.
After receiving a primary hepatitis B vaccine series, individuals with anti-HBs levels of 10 mIU/mL or more are considered protected and immune to the HBV, in accordance with CDC guidelines.

A negative result indicates a lack of recovery from acute or chronic hepatitis B or inadequate immune response to hepatitis B vaccination. Infants with a negative anti-HBs and a negative HBsAg should be revaccinated (refer to Chapter 4 for details). The ACIP does not recommend more than two hepatitis B vaccine series for non-responders.

Indeterminate results indicate an inability to determine if anti-HBs are present at levels consistent with immunity. Repeat testing is recommended in one to three months.

Refer to Appendix D for Interpretation of PVST.

Inconclusive Laboratory Results

Contact the reporting laboratory to clarify reports of inconclusive laboratory results, such as equivocal anti-HBs, and obtain appropriate follow-up instructions for re-testing.
Contact the ordering provider to confirm which labs were ordered to help determine Hepatitis B status and check Hepatitis B vaccine history.

Reporting Sources

One of the most difficult challenges for a PHBPP is obtaining reports of HBsAg-positive pregnant women. To have a successful reporting system, a PHBPP should have several overlapping sources of information to identify HBsAg-positive pregnant women. Three main reporting sources are laboratories, prenatal care providers and delivery hospitals.

Additional sources for reporting may include:

- Midwife centers/home births
- Pediatricians/Family Practices
- Planned Parenthood
- Federally Qualified Health Clinics (FQHCs)
- Rural Health Clinics (RHCs)

Laboratory Reports

A primary reporting source for the PHBPP is the laboratory. Nationwide, there are 260,000 certified laboratories under the 1988 Clinical Laboratory Improvement Amendments (CLIA). The objective of CLIA is to ensure quality laboratory testing for all lab testing performed on humans, except for research purposes. Laboratory reporting is more consistent and reliable than provider reporting and is often automatic or electronic. Additionally, reporting by laboratories can be made a condition of licensure, but non-laboratory reporting sources require constant reminders and education.

Several problems may be encountered using laboratory reporting as a source of perinatal cases, including:

- Provider information, including contact information, may be omitted
- Appropriate serology tests markers may not have been ordered
- Pregnancy status is often not indicated

Having alternate reporting sources can compensate for the deficiencies or periodic problems that may occur in laboratory reporting. When information is missing on the electronic lab report (ELR), the reporting laboratory should be educated on the information that is required by law for reporting of certain conditions. Refer to Chapter 3 for information pertaining to the statutes and rules of reporting.

Labor and Delivery Hospital Reports

The PHBPP also uses hospital reports to identify infants born to HBsAg-positive women. For a labor and delivery hospital to be an effective reporting source, it is necessary to educate the individuals responsible for determining a pregnant woman's HBsAg status, administering HBIG, and vaccinating the newborn. To achieve this, the program must collaborate with staff physicians, labor and delivery nursing staff, newborn nursery staff, pharmacy staff, and infection control staff. When possible, program assistance should be offered to develop hospital policies and procedures regarding screening and treatment standards that are reflected in Appendix E.

The PHBPP staff should encourage reporting by making the process as easy as possible and by helping the collaborating facilities in identifying what works best for them (e.g., whether reporting will be done by nursing staff or by infection control staff). Hospital staff designated to identify, and report cases should upload all cases at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/

The PHR and LHD program staff are responsible for completing the case management on all cases that are reported by hospitals.

Refer to flow charts located in Appendix C for the flow of information on serology testing and case management of HBsAg-positive women that must occur for the PHBPP to be successful.

Chapter 5 Learning Check

1. You are reviewing hepatitis B lab results for pregnant women. Which of the following lab results are you most concerned about?

   A. A woman with a positive HBsAg, positive HBeAg, and a HBV DNA of 250,000 IU/ml.
   B. A woman with a history of Hepatitis B vaccination and positive anti-HBs.
   C. A woman with fatigue who is HBsAg-negative.

   Answer: A. The positive HBsAg, positive HBeAg, and high HBV DNA viral load indicate a high level of circulating HBV and increased infectiousness. It is imperative this woman be educated, and that the delivery facility is prepared to administer appropriate PEP to her infant at delivery.

2. An infant born to a HBsAg-positive woman received three doses of hepatitis B vaccine and completed PVST, with the below results. How do you interpret the results and what is your recommendation?

- HBsAg: Negative
- Anti-HBs: Negative

   A. The infant is not infected with HBV and is protected from the virus.
   B. The infant is not immune to hepatitis B and should be considered a non-responder.
   C. The infant is not immune to hepatitis B and should receive a booster dose of hepatitis B vaccine, followed by PVST one-two months after vaccination.
   Or, if preferred, the infant can repeat the entire three-dose series.

   Answer: C. The infant did not respond to the first hepatitis B vaccine series and is susceptible. The infant should immediately receive a booster dose of hepatitis B vaccine and have PVST repeated one-two months later. Alternatively, the provider & family can decide to repeat the entire three-dose hepatitis B series and repeat PVST one-two months after the second series is complete.

3. A delivery hospital calls to ask for help in interpreting HBsAg lab results. A woman admitted for delivery was HBsAg-negative prenatally, but at her delivery HBsAg is now positive. What should the hospital do?

   A. Repeat the HBsAg before discharge to determine hepatitis B status.
   B. The result is most likely a false positive and the hospital does not need to do anything else.
   C. The infant needs HBIG and the hepatitis B birth dose within 12 hours of birth and be reported to the appropriate DSHS PHR or LHD.

   Answer: C. The positive HBsAg at delivery indicates a potential HBV infection that could be transmitted to the infant without appropriate PEP. This is true regardless of the prenatal HBsAg results. The PHBPP case manager can help determine true hepatitis B status by asking to see the results of the HBsAg confirmation by neutralization and by requesting other hepatitis B labs (anti-HBs, Anti-HBc, & IgM anti-HBc).

Chapter 6: Conducting Interviews, Counseling, and Education

Initialization of Interview

The client interview is crucial to the case management process. It includes educating the client patient on her condition and reassuring her that competent health care providers and public health staff will coordinate case management services for her, her infant(s), and her contacts 24 months of age or younger. Contacts older than 24 months of age will be referred to a provider for health care evaluation. In addition, the personal information that she shares with public health staff will be kept confidential, as required by law. The case manager should first verify with the ordering provider that the client has been informed of the positive HBsAg result prior to contacting the client. The case manager should not be the first person to inform the client of the positive results. When a case manager initially contacts the client, they should ask if the client has time to talk and, if she makes it known that it is an inconvenient time for her, the case manager should inquire about a more convenient day/time to reach her to conduct the interview.

The initial interview must include the following:

- Introduction of public health staff
- Role of the public health staff and the public health department, including the DSHS PHR or LHD office that will be managing her case
- Discussion with the client that her case managers are trained public health professionals and have experience assisting persons with hepatitis B in understanding and managing their disease
- Overview of hepatitis B, perinatal transmission, and the risks to her infant
- Review the Perinatal Hepatitis B Prevention Program (PHBPP), including the phases of the program and the timeframe of case management services provided by the program
- Discuss with the client that public health staff will ensure that her medical information remains confidential, as required by law

Providing Patient Assessment, Counseling, and Education

The purpose for patient assessment and education is to establish rapport, get the client accustomed to talking comfortably with you, addressing the client's concerns, gathering information, and giving the client sufficient information to support disease intervention behaviors. Targeted medical information presented by the provider or program staff can reduce or eliminate inappropriate strategies the client may develop to handle the diagnosis.

To conduct the assessment, the following should be done:

- First ask the client what she knows about hepatitis B.
- Provide information and education to the client regarding the disease, including:
  - Signs and symptoms of disease progression*
  - Preventing progression of liver disease
    - Avoiding or limiting alcohol consumption
    - Consulting a health care provider before beginning any medicine, including herbal remedies and over the counter (OTC) medications
    - Obtaining vaccination against hepatitis A
  - Transmission* and preventing transmission
  - Work and school exclusions are not necessary
  - Testing and treatment options
- Ask the client about problems or questions regarding hepatitis B and clarify any misconceptions.
- Discuss the meaning of the client's test result(s), and the possible need for additional testing. Give time to ask questions.
- Encourage the client to get involved with a support group to help her cope with her HBV infection.
- Explain that all household members 24 months of age or younger will be tested for hepatitis B, vaccine will be given if there is no valid vaccine record, and the contact is susceptible. In addition, these contacts will be case managed by the PHBPP until the vaccination series and PVST have been completed (may require two series of vaccine).
- Explain that all contacts older than 24 months of age should be referred to providers for medical evaluation.

*More detailed information regarding transmission can be found in Chapter 2 of this manual.

Supporting Program Compliance

It is important that the client understands the importance of the hepatitis B vaccine series and PVST to prevent infection of her infant(s). The case manager should reinforce messages expressed by the health care provider and verify that the patient understands and intends to comply with the program. The case manager should:

- Instruct the client to remind the delivery facility and care providers that she is a carrier of the HBV and that her infant(s) needs to receive HBIG and the hepatitis B vaccine at birth.
- Educate the client regarding the importance for the newborn(s) and other children in the household 24 months of age or younger to comply with timely completion of the hepatitis B vaccine series and subsequent PVST.
- Encourage the client to keep scheduled appointments and to notify the case manager when it is necessary to cancel or reschedule appointments.
- Encourage the client to contact the case manager with any changes to contact information or care providers (infant or mother).
- Obtain emergency contact information and complete disaster questionnaire. Ask if the client has any plans to move out of the state or out of the country during pregnancy or after delivery.

Providing Additional Patient Education Sources

- A critical aspect of the PHBPP is patient education. It is extremely important that program staff thoroughly explain to HBsAg-positive pregnant women and new mothers the serious consequences of HBV infection (found in Chapter 2), the lifesaving importance that hepatitis B biologics (HBIG and the hepatitis B vaccine) be administered to their infants, and the necessity of PVST after completing the vaccine series.
- The DSHS Immunization Section PHBPP has developed educational materials for HBsAg-positive women and their health care providers. These materials can be found at www.dshs.texas.gov/immunizations/what-we-do/vaccines/PHBPP.
- The CDC and the organization Hep B Moms have information about hepatitis B and perinatal hepatitis B available to order for free or to download in many different languages from:
  - https://www.cdc.gov/hepatitis-b/hcp/prenatal-provider-overview/?CDC_AAref_Val=https://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm
  - https://www.hepbmoms.org/copy-of-about

TIP: To build a trusting relationship with the client, follow up within one week of your initial interview to answer any questions or address any concerns she may have. Make note of this in your case management notes.

Chapter 6 Learning Check

1. True/False: Conducting an interview with a hepatitis B-positive pregnant or postpartum woman is optional.

   Answer: False. The initial interview is a crucial part of case management. Attempts at contacting the woman for her initial interview should be done within seven days of notification, but ONLY after the case manager confirms the woman has been informed of the results by the ordering provider.

2. All the following are ways to facilitate rapport during the interview except:

   A. Identifying the woman's preferred language prior to the interview and using translation services as needed.
   B. Introducing yourself and asking if this is a good time to talk before beginning the interview.
   C. Demanding the client answer all questions immediately since you have other work to do.
   D. Informing the client that all information will be kept confidential, as required by law.

   Answer: C. Clients that refuse to answer questions should be respected but still case-managed using information from their provider and the delivery hospital. Case managers should ask the clients if it is a good time to talk before starting the interview, and be respectful of clients' time, language needs, and concerns for privacy.

3. True/False: One good way to start the interview process is to ask, "What do you know about Hepatitis B?"

   Answer: True. Some women may have chronic hepatitis B or have been previously enrolled in PHBPP and may not need as much education. Other women may have never heard of hepatitis B prior to their positive result and will need more details.
   It saves time and improves the interview process to tailor education for each individual client.

Chapter 7: Case Management

What is Case Management?

Case management is a systematic process to ensure disease prevention through coordination of medical services and education. Case management uses an organized and coordinated service delivery approach, tailoring individualized and specific services to the needs of the client to facilitate continued support. The goal of PHBPP case management is to prevent perinatal hepatitis B transmission. Case managers achieve this goal through active disease surveillance, providing education to clients and health care providers, coordinating interventions needed to prevent transmission, and ensuring appropriate testing to determine the outcomes of cases.

The Texas DSHS, PHR and LHD office case managers should conduct case management for HBsAg-positive mothers, their infant(s), and household contacts 24 months of age or younger. Case management activities should occur according to the PHBPP guidelines.

Case management in the PHBPP involves:

- Interviewing HBsAg-positive mothers and providing education and information (e.g., brochures, handouts, and online resources) on hepatitis B and the PHBPP.
- Educating providers, facilities, contacts, and family members on hepatitis B and its prevention and control.
- Recommending that all women with chronic hepatitis B follow up with their primary care provider or specialist to monitor their hepatitis B.
- **NOTE:** Case managers do not need to obtain a physical referral but do need to remind women of the importance of regular hepatitis B evaluation.
- Collecting contact information (sexual and household) for appropriate referrals.

There are varying degrees of case management and each case may require different levels of involvement from DSHS. If the mother decides to follow up with her private physician, this is acceptable and should be encouraged. However, the case manager still has the responsibility of gathering all medical information from the provider, such as dates of vaccine administration (if applicable) and serology testing results. There can be many challenges and obstacles to case management, such as refusal of services by the client. Any problems encountered, and efforts made to overcome those obstacles, should be documented in case management notes.

Some clients may prefer or require more direct services, which may involve home visits to administer vaccines or to draw blood for testing. These services are provided by the PHBPP at no cost to the client. Services that are available to the HBsAg-positive pregnant woman, infant, and contacts will be discussed further in this chapter.

The DSHS PHR PHBPP Coordinators should review all case reports for completion prior to submission to the DSHS Immunization Section PHBPP.

All case management is documented within Salesforce. All current case management forms along with detailed instructions, can be found at https://www.dshs.texas.gov/immunizations/what-we-do/vaccines/hepatitis-b.
For additional guidance, contact your DSHS PHR PHBPP Coordinator.

Timeline for Management of Cases

Upon receiving notification of a positive HBsAg result in a pregnant woman, timing is important to ensure the appropriate steps are taken to maximize the health and safety of both the mother and child.
A general outline for when certain steps need to be taken is as follows:

Immediately:

- Contact the ordering provider to verify pregnancy status, get estimated due date (EDD) and planned delivery hospital
- Verify client has been informed of hepatitis B status prior to contacting client
- Contact client to interview or to set up a time for an interview.
- Send “Initial Provider Letter” to prenatal provider

Within Seven Calendar Days Of Notification:

- Open and submit mother case form
- Update information collected and document when interview is complete

Within 15 Days Of Notification:

- Complete interview or attempts to make interview have been done and documented in Salesforce
- Open and submit Contact Case form, as needed
  - Complete contact case management as needed until contact is closed
- Send follow up letter to client after initial interview is completed
- Create reminder to contact delivery hospital two months before EDD

Two Months Before EDD:

- Contact the mother to check in. Confirm EDD and planned delivery hospital.
  Remind the mother to inform the hospital of her hepatitis B status and that the infant needs HBIG and the hepatitis B vaccine immediately after birth
- Contact planned delivery hospital and inform them of the hepatitis B-positive client coming for delivery
  - Confirm the hospital has HBIG and the hepatitis B vaccine available, standing delegation orders (SDOs) for administering the vaccines, and SDOs to test every woman admitted for delivery for HBsAg
  - Remind hospital to upload patient information after delivery at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/
- Set up reminder to check with delivery hospital one week after EDD

Upon Notification Of Delivery:

- Review hospital reporting form and request additional information, as needed
  - Make sure infant received appropriate PEP. If infant did not receive appropriate PEP, contact facility to make plans to provide it and/or complete the "investigational report" and make plans to provide training
- Update mother's case form, and open and submit infant case form
  - Pay special attention to LBW infants and infants who do not receive the appropriate PEP. LBW infants need to re-initiate the hepatitis B series at one month of age. The birth dose does not count toward series completion. Infants that do not receive appropriate PEP, lag in program outcomes (PVST, completing the vaccine series on time) and may need more frequent follow-up within 30 days

Within Two Weeks Of Delivery:

- Contact mother/guardian to say congratulations and obtain the infant's name and pediatrician
- Send patient and provider reminder of the second hepatitis B vaccine dose
- Set up reminder to contact both the provider and mother/guardian one week before next vaccine is due

One Week Before The Second Hepatitis B Vaccine Dose Is Due:

- Remind both the provider and the mother/guardian that the vaccine is due.
  Make note of next appointment. If the infant does not have an appointment, help the mother/guardian make one and offer LHD office/home-visit services, as needed
- Ask provider to send a copy of the vaccine record after administration with the date of administration, formulation, manufacturer, and lot number to https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/

Upon Notification Of Second Vaccine Dose:

- Review vaccine record and verify the dose. If there are any problems, immediately contact the provider
- Update and submit the infant case form
- Set up reminder to contact both the provider and mother/guardian one week before the next vaccine is due

One Week Before The Third Hepatitis B Vaccine Dose Is Due:

- Remind both the provider and the mother/guardian that the vaccine is due. Make note of next appointment. If the infant does not have an appointment, help the mother/guardian make one and offer Local Health Department (LHD) office/home-visit services, as needed
- Ask provider to upload vaccine record after administration with the date of administration, formulation, manufacturer, and lot number at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/

Upon Notification Of Third Vaccine Dose:

- Review vaccine record and verify the dose. If there are any problems, immediately contact the provider
- Update the infant case form
- Set up reminders to contact both the provider and mother/guardian one week before PVST is due

One Week Before PVST Due:

- Remind both the provider and the mother/guardian that PVST is due. Make note of next appointment. If the infant does not have an appointment, help index case make one and offer LHD/home visit services as needed
- Ask provider to upload lab results as soon as they receive them at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/

One Day After Scheduled PVST:

- Contact ordering provider to ask for PVST results. If they have not yet returned, verify the provider ordered HBsAg (CPT code: 87340) and Anti-HBs (Quantitative CPT code: 86317)
- Review lab results. Verify correct labs were ordered and determine if the infant is immune, susceptible, or infected
  - If the infant is infected, report the infant to PHBPP within one working day
  - If the infant is susceptible, contact the provider to discuss the booster dose and repeat testing protocol. (See Chapter 7 for more information)
- Update infant case form with a copy of the PVST lab results.
- If the child is immune, case management is complete. Notify the mother/guardian of the results and send “reminder of program completion”

How to Manage Cases

All Case Management Occurs Within The PHBPP Salesforce Database

The Texas DSHS PHBPP has created an online database in which statewide PHBPP staff can identify new cases, manage existing cases, and run reports. The goal of the database is to provide a uniform statewide platform and streamline the work and reporting required by the program.

Getting Started

Logging In As A Regional Coordinator

1. To access the PHBPP database, use the following url: https://txhhs.lightning.force.com/lightning/page/home
2. Bookmark this webpage for future use.
3. All Regional Coordinators will need to use the authenticator app or IAMOnline to gain access. To set up your authenticator, refer to the Authenticator presentation to choose the best application for you.
4. After setting up the authenticator, return to the PHBPP database.
5. Log in to the database. Your username is your work email. You will be prompted to generate a password.

Logging In As Local Health Department Staff

1. To access the PHBPP database, use the following url: https://txhhs.force.com/DSHSPeriHepBPrevention/s/login/
2. Bookmark this webpage for future use.
3. Log in to the database. Your username will be your work email .phbpp. I.e. “Johnsmith@workemail.phbpp” You will be prompted to generate a password.

Refer to the Perinatal Hepatitis B Prevention Program Online Database Manual for system navigation.
As of August 1, 2022, all Case Management will be taking place within Salesforce.
The PHBPP Salesforce database assigns mothers a PHBF number automatically.

- All Case Forms are built within one Mother Record.
  - Mother Records are generated from NEDSS, Hospital/Provider Forms, Transfers, PHB Database users.
- Mother Case Forms are created for each potential case.
  - If eligible, the database user will confirm EDD or infant DOB.
- Infant Case Forms are created once the infant is born.
- Household Contact Forms are created for any individual less than or equal to 24 months of age residing with HBsAG+ person.

The previous format for the ID number is: yr/county/mother/hh##, and was assigned as following:

- **yr:** The four-digit year the client was first identified in the PHBPP (i.e., yr:2019).
- **county:** The three-digit FIPS county code.
- **mother:** The three-digit individual code, as assigned by the case manager (this is a chronological number unique to every individual)
- **hh##:** The two digit-number identifying the relationship to the mother. The mother's ID must end with "00".
  - Infant: 01-09 (based on current pregnancy only)
  - Contacts 24 months of age and younger.

There is a field within Salesforce for the ID number, however, it is no longer required.

The Initial Record

Upon opening a case, check database for mothers' record, if one is not found, please open a mothers record first, then the mother's case form should be created and filled out with all available information and submitted within one weekday. All case management is documented in Salesforce. When initially creating a case form, the required information for opening a case is:

- Initial report date
- Initial contact date
- Mother's full name
- Mother's DOB
- Mother's address
- Provider information (name and contact info)
- Estimated Date of Delivery/EDD or infant DOB and pregnancy outcome.
- HBsAg-positive lab report with confirmation

Requested information that may be gained from the client interview, but not required for the initial creation of case form, is:

- Phone number
- Country of birth
- Mother's maternal grandmother's country of birth
- Planned delivery hospital
- Race
- Preferred language
- Insurance information
- Alternate contacts
- Disaster Questionnaire
- Vaccine history as applicable
- Prior hepatitis B lab results

Contacting The HBsAg-Positive Pregnant Or Postpartum Woman

Establishing contact and developing a trusting relationship with the HBsAg-positive client is critical and is the first step in the case management process. She should be contacted as soon as possible following identification, preferably by phone.

NOTE: The case manager should not be the first person to inform the client of the positive results. Contact the provider first to determine whether they have notified the client and provided any counseling or education. If they have not, request they notify her of the results and that the DSHS PHR or LHD will be contacting her to follow up. Call the provider again later to verify it has been done.

To establish a trusting relationship with the client, advise her that all information she provides will be kept confidential, as required by law. If the client is reluctant to provide information, the physician's office can be contacted to provide additional needed information. Remember, client consent is not required to obtain laboratory confirmed HBsAg test results from the provider.

If you are encountering challenges while attempting to contact the client for case management services, refer to Table 7.1 on page 62 for related actions.

Best Practices:

- Notification(s) may be in any of these forms:
  - Phone call(s), with messages if there is no answer – preferred method,
  - Letter(s) sent to parent(s), and
  - Computer/phone system that automatically calls or texts patients.
- Remind parents and provider one week before immunization visit(s).
- Contact provider within one day after scheduled appointment to ensure that patient received necessary vaccine(s)/PVST.
  - Verify the provider ordered the correct PVST labs and ask them to correct the lab orders, as needed. Many labs can add testing to existing samples within five days, to prevent additional lab draws.
- If the appointment is missed, contact parent(s) immediately to arrange for a follow-up visit or a home visit.

Challenges Contacting the HBsAg-positive Mother	
Challenge	**Follow-up Action**
No answer of telephone calls	Make at least five attempts to call on different days of the week, at different times of the day. If possible, attempt at least one evening call.
Telephone number is disconnected	Contact the provider to verify contact information. Inquire how they have been contacting her. Check Immtrac2 and NEDSS for other possible numbers. If no new number can be obtained, a first-class letter should be sent to the client's home address. It should include contact information and request the client contact case management directly regarding a recent health issue (do not disclose HBsAg results in letter).
No response to first-class United States Postal Service (USPS) letter	Send a certified letter, signature required, to the client's home address. It should include contact information and request the client contact case management directly regarding a recent health issue (do not disclose HBsAg results in letter).
Certified letter returned with "Forwarding Address Requested" stamp	Send a certified letter, signature required, to the client's forwarding address. It should include contact information and request the client contact case management directly regarding a recent health issue (do not disclose HBsAg results in letter).
No response after certified letter sent to forwarding address	Attempt to visit the last known residence to conduct a home visit and provide education. Know the patient's preferred language or arrange for interpretation.
Unsuccessful home visit/no one home	Work directly with the provider's office to manage the case. Request the provider educate the client on the importance of the case manager's role in preventing transmission of the virus to her infant.
Inability to contact client after exhausting all above options.	Do not close as "lost to follow-up." If the patient cannot be contacted, but you have an EDD and planned delivery hospital, attempts must still be made to locate the infant around the time of delivery. More information may become available after delivery (e.g., Vital Statistics records).
Client moved to a known address in another jurisdiction/ state.	Obtain accurate location information, complete the appropriate transfer form and submit to the DSHS Immunization Section, PHBPP Central Office. PHBPP will forward the transfer information to the new jurisdiction. All out-of-state transfers should be sent to Central Office for the coordinator to transfer.
Client moved to an unknown address in another state.	Contact Central Office for assistance. They will attempt to coordinate with the new state for the new address and transfer of case. If the new address is unable to be identified and the client cannot be located, the new state may not accept the transfer. The case is then closed as "Lost to follow-up".

Table 7.1 Challenges Contacting the HBsAg-positive Mother

Other methods that may be used to locate the client include:

- Check ImmTrac2 to check for additional/updated demographic information and to find current pediatric provider.
- Contact the post office to see if there is a forwarding request for the client.
- Make a home visit to the last known address, if there is no response to certified letters.
  - **NOTE:** Find out from the provider what the patient's preferred language is and arrange for interpretation, if needed, to avoid any barriers when first contacting the patient.
- Check NEDSS for new labs or demographic information and/or contact the laboratory providing the test results for contact information on the patient.
- Access Accurint, an online searchable database available to law enforcement, and government agencies. Accurint includes postal addresses, driver's licenses, property ownership, and criminal records. To use this database, you must request the assistance of DSHS PHR or LHD Sexually Transmitted Disease (STD) program staff.
- Contact Medicaid and WIC programs, as up-to-date addresses are required for these services.

A case cannot be closed as 'lost to follow-up' until all avenues have been exhausted. Additionally, the patient must no longer be receiving any known services from an OB/GYN due to the physician's inability to locate or contact the client for services, however, if the patient cannot be contacted but you have an EDD and a planned delivery hospital (from client or physician), attempts must still be made to locate the infant around the time of delivery before the case can be closed.
After the EDD has passed and the planned delivery hospital does not have record of the birth, contact central office PHBPP staff to see if the mother/infant's birth hospital or contact information can be located in Vital Statistics records.

Patient Education

A critical aspect of the PHBPP is patient education. It is extremely important that PHBPP staff explain to HBsAg-positive pregnant women and new mothers about the serious consequences of HBV infection (refer to Chapter 2), the lifesaving importance of hepatitis B biologics (HBIG and the hepatitis B vaccine) being administered to their infants, and the necessity of PVST after completing the vaccine series. The DSHS Immunization Section PHBPP has developed educational materials for HBsAg-positive women and their health care providers.
Materials can be found at www.texasperinatalhepb.org.

Case Management Of HBsAg-Positive Pregnant And Postpartum Women

Each DSHS PHR and LHD staff involved with the interviewing of clients should explain the services provided by the PHBPP and assure the client that her medical history (including her household contacts 24 months of age and younger) will be handled confidentially by the PHBPP staff. Create a new mother's case form in Salesforce, it should be entered within one week, including the following information:

- Planned delivery hospital.
- Vaccination history (if available)
- Pregnancy history (if applicable)
- Treatment(s) and/or medication(s) for hepatitis B
- Any referrals to specialist(s) for hepatitis B

1. Face sheet showing patient's contact and insurance information.

   NOTE: Occasionally, the LHD will be notified of new hepatitis B-positive woman by a delivery hospital. Request the hospital upload delivery notification at https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/
2. Verify that the provider has notified the client of her positive HBsAg result. Establish the clients preferred language before contacting her. Utilize translation language services when appropriate.
3. Contact the client to obtain pertinent medical history, personal information, and type of insurance (Medicaid, private insurance, no insurance). All efforts should be made to obtain patient insurance information, otherwise, the reason for not obtaining the insurance status should be documented.
   NOTE: Insurance information is normally noted on the "face sheet," obtained from the client's provider.
4. Educate the client about HBV, communicability of the virus, and the importance of protecting her infant from HBV transmission using HBIG and the hepatitis B vaccine.

   NOTE: HBV education regarding routes of HBV transmission should be done prior to requesting information on all sexual partners and household contacts.

5. Services that will be provided by the DSHS PHR and/or LHD should be explained to the client and, if needed, a face-to-face visit should be arranged. If the client is unable to travel to a DSHS PHR or LHD, the PHBPP staff can conduct home visits to provide these services, in accordance with their LHD policies.
6. Provide patient educational brochure to the client, the bilingual "Hepatitis B Vaccine Can Save Your Baby's Life Brochure", (Stock # 11-11444), available through the DSHS Immunization Section PHBPP at https://secure.immunizetexasorderform.com/default.asp. Ensure that all educational materials are provided in a culturally sensitive manner.

   TIP: The group Hep B Moms has hepatitis B and perinatal hepatitis B information available in many different languages and available free on their website at: https://www.hepbmoms.org/brochures.
7. Refer the HBsAg-positive pregnant woman to her usual health care provider (PCP or OB/GYN) if she needs a referral for additional hepatitis B care.

   NOTE: The health care provider or OB/GYN might refer the HBsAg-positive pregnant woman to a gastroenterologist, hepatologist, or an infectious disease specialist. Her case should continue to be managed, regardless of which specialty is following her.

   - If the HBsAg-positive pregnant woman receives antiviral medications for hepatitis B, document the following information on her case management form:
     - treatment or antiviral agents (brand and dose)
     - date antivirals were initiated
8. Notify the client's health care provider (or other specialty provider) of the role of the DSHS PHR and/or LHD, including the case management services, that will be provided to the newborn and household contacts 24 months of age and younger.
9. Create a Mother Case Form within one week.
10. Identify all household contacts who are 24 months of age and younger, sexual partner(s), and household contacts 24 months of age and older.
    - PHBPP Case Management services should be provided for all household contacts 24 months of age and younger.
    - All sexual partners and contacts 24 months of age and older should be referred to a health care provider for follow-up and evaluation. Adult contacts without health insurance who are found to be susceptible to hepatitis B can be vaccinated through the Adult Safety Net (ASN) program. Susceptible children may be eligible for Texas Vaccines for Children (TVFC) program. Please contact your DSHS PHR or LHD for additional information.
11. After the initial interview with the pregnant woman, direct program involvement with her may be minimal. However, because the client may be newly diagnosed, program personnel should remain available to offer counseling or advice and to answer any questions or concerns she may have.
12. If possible, notify the delivery hospital where the client plans to deliver her infant(s) at least two months prior to her estimated date of delivery.
13. Ensure that the hospital has both HBIG and hepatitis B vaccine available in advance, at least seven days before her estimated date of delivery.

14. Review with the newborn nursery their standing orders and written policies pertaining to both the administration of HBIG and hepatitis B vaccine birth dose, and the testing of the infected mother for HBsAg on delivery.
15. Periodically contact the hospital (delivery unit or newborn nursery) to determine whether the mother has yet delivered.
16. Once the infant has been born, add an infant form within 15 days of the infant's birth. **NOTE:** Case management on HBsAg-positive women with a stillbirth or miscarriage will still be case managed by the program, however, they should be referred to a health care provider for health care to delay further injury to the liver. Update the Mother's Case Form and close the case as "referred to medical follow-up," and the status code is noted as "infected."

Provider Education

Patients with acute and chronic HBV infections require medical evaluation and regular monitoring. PHBPP case managers should refer all HBsAg-positive pregnant women to medical providers for supportive and/or therapeutic treatment to prevent the progression of liver damage. PHBPP case managers do not need to get a physical referral, but only need to educate the client to follow-up with their specialist or primary care physician for regular monitoring. If they are not already familiar in doing so, the provider should also be educated as to:

- interpretation of serology results (refer to Appendix D)
- monitoring patients for disease progression and prevention
- identifying the need for specialized consultation

If the pregnant woman's infection has been verified as being chronic, the PHBPP staff should identify available medical resources for chronic hepatitis B infections and ensure the medical providers are knowledgeable about risk factors for HBV infection in pregnant women, their infants, sexual partners, and household contacts. If needed, staff should provide training to the providers. Pregnant women, infants, sexual partners, and household contacts older than 24 months of age should be referred to a FQHC or a RHC for appropriate medical management if they do not already have a health care provider.

Client And Provider Reminders

Due to the critical need to complete the hepatitis B vaccine series and PVST on time, reminders are required to remind parents as to when vaccinations and serology testing for their infants are due. It should never be assumed that parents will use effective methods of reminders for themselves, and physicians' offices should not be relied on for notification of appointments. To be effective, the system should be set up to make it easy to remind the coordinators, who can then notify clients, when an immunization or test is due. Notifications to parents and providers should occur at least one week prior to any hepatitis B vaccine and/or PVST due dates.

Case Management Of Infants Born To HBsAg-Positive Women

Case management of infants born to HBsAg-positive women can be labor intensive. Adequate case management should require no more than nine months to complete perinatal hepatitis B prevention case management services once the infant has been born. (Refer to Guideline 3 in Appendix C.) For children who do not adequately respond to the vaccine series and who are also not infected with HBV, case management services may take up to 17 months to complete. Infants born to women whose hepatitis B status remains unknown indefinitely (e.g., safe surrender) also need to be case managed to ensure they receive the hepatitis B vaccine series and PVST.

1. It is imperative that the case manager inform labor and delivery staff at the planned delivery hospital of the woman's HBsAg-positive status at least two months prior to her expected delivery date.
    - Staff should ensure that the delivery hospital has both HBIG and hepatitis B vaccine ready for administration to the newborn immediately after delivery, to be given within 12 hours.
    - Hospitals should order HBIG and hepatitis B vaccine directly from the distributor. HBIG can be ordered through the DSHS Immunization Section only in emergency situations. Refer to guidelines provided later in this chapter.
2. Appropriate Post-Exposure Prophylaxis (PEP) treatment should be administered, based on the mother's HBsAg status:
    - Born to HBsAg-positive woman:
        - Administer HBIG within 12 hours.
        - Administer first dose (birth dose) of hepatitis B vaccine within 12 hours.
    - Born to HBsAg-unknown status woman:
        - Administer first dose (birth dose) of hepatitis B vaccine within 12 hours.
        - If mother's hepatitis B status is still unknown at discharge, administer HBIG before discharging infant.
        - If HBIG was not given before discharge and the HBsAg result later comes back as positive, administer HBIG no later than seven days after delivery.
            - If the infant has already been discharged, it is the delivery facility's responsibility to recall the infant and administer HBIG as soon as possible.
    - Born to a woman with discrepant prenatal and delivery HBsAg results:
        - If any HBsAg test has been positive, administer:
            - HBIG within 12 hours
            - First dose (birth dose) of hepatitis B vaccine within 12 hours
            - **NOTE:** Infants born to HBsAg-positive women do not need placement in special isolation. (For additional guidance on PEP and vaccine schedules, refer to Appendix B). It is generally safe for HBsAg-positive mothers to breastfeed their infants. (For additional information, refer to the Perinatal Transmission section in Chapter 2).

3. The case manager should obtain all necessary information below about the first dose of the HBIG and Hepatitis B vaccine from the delivery facility.
    - Lot number
    - Manufacturer/Brand
    - Dose
    - Date and time of administration
4. Information should be documented on Infant Case Form within Salesforce. The Infant Case Form must create within 15 days of infant birth.
5. Before the infant leaves the hospital, discharge planning should begin. The case manager should find out from the delivery facility which pediatrician the infant is being discharged to. Once that information is known, arrangements should begin to ensure the timely administration of the second and third doses of hepatitis B vaccine.
6. Reminders should be sent to the family and pediatric health care provider to notify them when vaccines and PVST are due. For additional information, please refer to the earlier Client and Provider Reminders section of this chapter.
7. The infant should complete the hepatitis B vaccine series on time.
8. Dose Two: at one month of age (no later than two months of age).
9. Dose Three: at six months of age.
    - Refer to Appendix B for further guidance on vaccine schedules. The infant should be vaccinated through his/her pediatrician. If the child is unable to be vaccinated by the pediatrician, the case manager should arrange with the DSHS PHR PHBPP Coordinator and/or the DSHS Immunization Section to obtain the vaccine. Infants born to HBsAg-positive mothers can receive DSHS Immunization Section-supplied vaccine, even if they receive health care in the private sector.
10. The immunization information should be obtained from the infant's healthcare provider and be documented on the "Infant Case Form". If the parents consented to ImmTrac2, vaccine information can also be obtained from this system. All vaccine updates, should be immediately documented within Salesforce.
    - date administered
    - dose administered
    - formulation (ie., Pediarix®, Engerix-B®, Recombivax HB®, etc.)
    - manufacturer
    - lot number
    - provider/clinic that administered the dose
11. Contact the parent or guardian by phone or mail to remind him/her about PVST at the child's nine month wellness visit.

12. Results of the PVST is needed to determine the success of PEP.
    - Perform no earlier than nine months of age
    - Perform at least one to two months after completion of the hepatitis B vaccine series
    - Two lab tests are required:
        - HBsAg, CPT Code: 87340 and anti-HBs, CPT Code: 86317
    - Test at the nine-month-old well-child visit, if all doses of the vaccine were completed at least one to two months prior.

      NOTE: Request that the provider annotates and flags the child's medical record to indicate that the PVST (HBsAg and anti-HBs) is due at the next well-child visit (see guidance above for timing). If an appointment date has not yet been scheduled, also follow up with the parent or guardian to schedule an appointment with the provider.

      NOTE: Follow up with the provider one day after the appointment for PVST is scheduled to verify the child attended and that the correct lab tests were ordered. If ordered incorrectly, many laboratories can add the correct testing to existing specimens for up to five days to prevent needing to do additional blood draws on the infant.

- A release of information is not needed from a parent or guardian to request that the provider perform PVST on the infant. Hepatitis B, identified prenatally or at delivery, is a reportable condition and is protected under Texas statutes and rules. Because of the significant health risks posed to the infant if proper care is not obtained, a release of information is not required to provide this information to the infant's care provider. Ideally, the hospital and/or DSHS PHR or LHD should notify the infant's care provider immediately after birth.
- PVST is not recommended before the age of nine months to avoid possible detection of anti-HBs from HBIG administered during infancy, and to maximize the likelihood of detecting late HBV infection. Quantitative antibodies for surface antigen are preferred because they give a level of immunity with which to measure the immunity of the infant. Anti-HBc testing of infants is not recommended because passively acquired maternal anti-HBc may be detected up to age 24 months in infants born to HBV-infected mothers.

13. The results of the tests should be recorded on the Infant Case Management Report form and the form should be immediately submitted to the DSHS Immunization Section PHBPP, along with a copy of the infant's results.

Perinatal Hepatitis B Virus Infection Case Definition

Perinatal hepatitis B infection in infants ages one to 24 months is a nationally notifiable condition, and Texas is required to report all cases to the CDC. These cases are reported through NEDSS AND PHBPP. The case definition for perinatal hepatitis B virus infection is HBsAg positivity in an infant aged one to 24 months, or an infant aged nine to 24 months who is positive for HBeAg or HBV DNA, born in the US or US territories to a hepatitis B-positive mother. An infant who is determined to be HBsAg-positive will be classified as a case of perinatal hepatitis B virus infection. Perinatal hepatitis B infection in the newborn may range from asymptomatic to fulminant hepatitis. All laboratory-confirmed perinatal hepatitis B virus infections must be reported to the DSHS through NEDSS and through the Perinatal Hepatitis B Program. It is the responsibility of the DSHS PHR and LHD program staff to obtain a copy of the laboratory report, update the Infant Case Management Report form, and submit both forms to the DSHS Immunization Section PHBPP Coordinator within one working day of notification.

Case Management Of Contact(s) 24 Months Of Age Or Younger To HBsAg-Positive Pregnant Women

Household contacts are defined as persons 24 months of age or younger currently residing in the home of the HBsAg-positive pregnant woman. Household contacts older than 24 months of age and sexual contacts are not eligible for the program and should be referred to a health care provider. The Contact 24 Months or Younger Case Management Report form should be completed for all contacts identified who are 24 months of age or younger, and case management should be completed.

These case management procedures should be followed when a contact 24 months of age or younger is identified as born to a positive HBsAg mother.

1. Educate parent/guardian on the consequences and risks of HBV infection.
2. Create the Contact 24 months of age or younger Case Report Form for each contact 24 months of age or younger identified within 15 days of identification.
3. Obtain vaccine and serology history on all contacts 24 months of age or younger. A reliable vaccination history for each dose administered to complete the hepatitis B vaccine series should be obtained, if applicable. Serology history consists of a written and dated laboratory report; verbal reports are not acceptable. Case management is initiated based on vaccine results and serology history.
   - If contact 24 months of age or younger has no documentation of immunity by serology, the contact should be tested for HBsAg and anti-HBs. Once the results are obtained, follow guidance identified on Chart 7.2. HBsAg-positive results must have confirmatory testing performed.

Actions After First PVST Results			
HBsAg	Anti-HBs	Status	Action
Negative	Negative	Susceptible	Proceed to Step four below
Negative	Positive	Immune	Submit form and documentation to DSHS PHR PHBPP Coordinator
Positive	Negative	Infected	Refer to physician for follow-up and evaluation

Chart 7.2 Actions after First PVST Results

4. If needed, ensure initiation and completion of the hepatitis B vaccine series. If the contact is susceptible after a complete hepatitis B vaccine series, give a booster dose of the hepatitis B vaccine and then repeat PVST one-two months later. If the contact is still susceptible after the booster dose, give dose two and three of the second Hepatitis B vaccine series and then repeat PVST one-two months later. Alternatively, the provider and family can choose to not do a booster dose and just repeat the entire three-dose hepatitis B vaccine second series, with PVST repeated one-two months after the last vaccine. The CDC does not recommend further vaccination after completion of two complete hepatitis B vaccine series. These "non-responders" should be referred to their physician for follow up.
5. All updates to the ***Contacts 24 months of age or younger Case*** form should be submitted immediately. DSHS PHR PHBPP Coordinators must submit reports to the DSHS Immunization Section PHBPP Coordinator.

Perform PVST one-two months after completing the vaccine series to determine if adequate protection has been achieved with one complete series of vaccine, keeping in mind that PVST should not be done before nine months of age. Refer to Chart 7.3 for relevant actions for each type of PVST result.

Actions After 2nd PVST Results 6.0			
HBsAg	**Anti-HBs**	**Status**	**Action**
Negative	Negative	Susceptible/ Non-responder	Provide counseling and refer to provider
Negative	Positive	Immune	Submit form and documentation to DSHS PHR-PHBPP Coordinator
Positive	Negative	Infected	Refer to provider for follow-up and evaluation

Chart 7.3 Actions After Second PVST Results

6. Record all information on the Contact Case form. Any updates should be documented within Salesforce.

NOTE: Reporting of adequate and inadequate is acceptable only if your lab is using mIUs as the measurement for anti-HBs and the cut off is less than ten for reporting inadequate anti-HBs, and ten or more for reporting adequate anti-HBs. Check with your lab to be certain of results.

Case Management Report Submission Guidelines

Initial identification of cases should be submitted on their respective case management reporting forms within 15 days.

All case management report updates must be submitted immediately to the DSHS PHR PHBPP Coordinator for any the following events:

- Administration of any dose of hepatitis B vaccine
- Completion of PVST
- Any added or updated information to any part of the form
- Closure of a case

Chapter 7 Learning Check

1. A HBsAg positive pregnant women lives with her 32-year-old husband, one-year-old daughter, and three-year-old son. How do you case manage the members in the household?

   A. Each household contact should be referred to their PCP for vaccination and testing as needed.
   B. Only the one-year-old should have a case management report opened and complete the hepatitis B vaccine series and PVST.
   C. All household contacts should have a case management report opened and complete the hepatitis B vaccine series and PVST.
   D. Both children need to have a case management report opened and complete the hepatitis B vaccine series and PVST.

   Answer: B. PHBPP case management services are provided for all household contacts 24 months of age or younger. Only the daughter is under less than 24 months of age and eligible for case management services. She should be vaccinated and receive PVST as needed. All other contacts should be referred to their PCP for evaluation, vaccination, and testing as needed.

2. True/False: In order to close out a PHBPP case as "referred for medical follow-up," the case manager needs to give the client an official referral for a specialist.

   True or False?

   Answer: False. Case managers do not need to obtain an official referral but do need to remind women of the importance of regular evaluation. Instructing the client to have regular hepatitis B evaluations done with their primary care provider or specialist is sufficient to close as "referred for medical follow-up."

3. PVST requires which of the following the following lab tests?

   A. HBsAg
   B. Anti-HBs
   C. Both A and B
   D. Hepatitis Panel

   Answer: C. PVST consists of HBsAg and Anti-HBs. A hepatitis panel is not recommended because it usually only tests for markers of an acute infection and not immunity. Note that Anti-HBc is also not recommended because infants can passively acquire it from their HBsAg positive mothers for up to 24 months.

Chapter 8: Contacts and Resources

Contact Information

For a complete list of names and email addresses, please visit the DSHS Immunization Section PHBPP website at www.texasperinatalhepb.org. Refer to Appendix A for a map defining the borders of each Texas region.

DSHS Immunization Section PHBPP Coordinator:

Phone: 512-776-6035
Fax: 512-776–7544

DSHS Immunization Section PHBPP Central Staff:

Phone: 512-776–6813
Fax: 512-776–7544

DSHS PHBPP Coordinators:

Regions 1/9/10
Phone: 432-571–4146
Fax: 432-571–4162

Regions 2/3/7
Phone: 817-692-4807
Fax: 512-483-3920

Regions 4/5/6
Phone: 903-520-8146
Fax: 903-877-2625

Region 8
Phone: 830-433-1283
Fax: 830-278–1831

Region 11
Phone: 956-423–0130 Ext. 5549
Fax: 956-444-3216

Suggested Publications

Red Book 2024:
https://publications.aap.org/aapbooks/monograph/756/Red-Book-2024-2027-Report-of-the-Committee-on

DSHS Resources	
DSHS Home page	www.dshs.texas.gov
DSHS Salesforce Link for LHD	https://txhhs.my.site.com/DSHSPeriHepBPrevention/s/login/
DSHS Online Portal	https://txhhs.my.site.com/DSHSPeriHepBPreventionPortal/s/
DSHS Adult Safety Net Program	http://www.dshs.state.tx.us/asn/
DSHS PHBPP	www.texasperinatalhepb.org
Emerging and Acute Infectious Disease Unit	www.dshs.texas.gov/idcu/
Immunization Section	www.ImmunizeTexas.com
Immunization Section Literature Order Form	secure.immunizetexasorderform.com/default.asp
ImmTrac2	www.dshs.texas.gov/immunize/immtrac/
Texas National Electronic Disease Surveillance System (NEDSS)	txnedss.dshs.state.tx.us:8009/login/login.asp
CDC Resources	
Home page	www.cdc.gov
ACIP	www.cdc.gov/vaccines/acip/index.html
Annual Statistics and Surveillance Reports	www.cdc.gov/hepatitis/statistics/SurveillanceRpts.htm
Hepatitis B Virus information	www.cdc.gov/hepatitis/hbv/index.htm
Morbidity and Mortality Weekly Reports (MMWR)	www.cdc.gov/mmwr
National Health and Examination Survey	www.cdc.gov/nchs/nhanes.htm
Recommended Immunization Schedule	www.cdc.gov/vaccines
Vaccine Information Statement	www.cdc.gov/vaccines/hcp/vis/index.html
CDC, 2021. "Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook" 14th Ed. (2021).	www.cdc.gov/vaccines/pubs/pinkbook/hepb.html
Taken from "Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the ACIP", Sarah Schillie, MD; Claudia Vellozzi, MD; Arthur Reingold, MD; et al., MMWR, January 12, 2018, Vol 67,(1);1-31	www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm

Other Resources	
American Academy of Pediatrics (AAP)	www.aap.org
American College of Obstetrician and Gynecologist (ACOG)	www.acog.org
American Liver Foundation	www.liverfoundation.org
Asian Liver Center at Stanford University	www.med.stanford.edu/liver.html
GlaxoSmithKline	www.gskvaccines.com
Healthfinder	www.healthfinder.gov
Hepatitis B Foundation	www.hepb.org
Hep B United	www.hepbunited.org
HepBMoms	www.hepbmoms.org
Hepatitis Foundation International	hepatitisfoundation.org/
Immunization Action Coalition (IAC)	www.immunize.org
IAC Hepatitis B Birth Dose Honor Roll	www.immunize.org/honor-roll/birthdose/
Institute for Vaccine Safety (Johns Hopkins School of Public Health)	www.vaccinesafety.edu
Medscape	www.medscape.com
Merck & Co., Inc.	www.merck.com
National Library of Medicine (links to MedlinePlus and PubMed)	www.nlm.nih.gov
Sanofi Pasteur ImmYOUnity Vaccine Information	https://www.sanofi.us/en/your-health/products/vaccine-products
Vaccinate Your Family (formerly Every Child by Two)	www.vaccinateyourfamily.org
World Health Organization (WHO) Hepatitis B Key Facts	www.who.int/en/news-room/fact-sheets/detail/hepatitis-b
Zip Info FIPS Code Search	https://www.zipinfo.com/cgi-local/zipsrch.exe

Free Newsletters and Publications	
The following resources about immunization and hepatitis B may be downloaded or ordered directly from the organizations listed:	
CDC Morbidity and Mortality Weekly Report (MMWR)	www.cdc.gov/mmwr
CDC Pink Book-Epidemiology and Prevention of Vaccine-Preventable Diseases	http://www.cdc.gov/vaccines/pubs/pinkbook/index.html
IAC Publications	www.immunize.org/publications
Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the ACIP	www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm

Appendix A: Program Terms, Definitions, and Regions

Terms and Definitions

Serology Tests

Anti-HBc: Hepatitis B Core Antibody

Anti-HBe: Hepatitis B “little e” Antibody

Anti-HBs: Hepatitis B Surface Antibody (HBsAb)

HBcAg: Hepatitis B Core Antigen

HBeAg: Hepatitis B “little e” Antigen

HBsAg: Hepatitis B Surface Antigen

IgM: M-class Immunoglobulin Antibody

Symbols

(<): less than/younger than

(>): greater than/older than

(≤): less than or equal to/younger than or equal to

(≥): greater than or equal to/older than or equal to

Terms and Acronyms

AAFP: American Academy of Family Physicians

AAP: American Academy of Pediatrics

ACIP: Advisory Committee on Immunization Practices

ACOG: American College of Obstetricians and Gynecologists

CDC: Centers for Disease Control and Prevention

CFR: Code of Federal Regulations

CLIA: Clinical Laboratory Improvement Amendments

DNA: Deoxyribonucleic Acid

DSHS: Texas Department of State Health Services

EDD: Estimated Date of Delivery/Estimated Due Date

EMR: Electronic Medical Record

FDA: Food and Drug Administration

FIPS: Federal Information Processing Standard

FQHC: Federally Qualified Health Center

GSK: GlaxoSmithKline

HB: Hepatitis B

HBIG: Hepatitis B Immune Globulin

HBV: Hepatitis B Virus

HIPAA: Health Insurance Portability and Accountability Act

HIV: Human Immunodeficiency Virus

IIS: Immunization Information System

IM: Intramuscular

ImmTrac2: Texas Immunization Registry

IT: Information Technology

ITEAMS: Inventory Tracking Electronic Assets Management System

IV: Intravenous

LHD: Local Health Department

MSM: Men who have sex with men

NAM: National Academy of Medicine (formerly IOM, Institute of Medicine)

NEDSS: National Electronic Disease Surveillance System

NHANES: National Health and Nutrition Examination Survey

NIS: National Immunization Survey

NPI: National Provider Identifier

OB-GYN: Obstetrician/Gynecologist

OTC: Over-the-counter

PCR: Polymerase Chain Reaction

PEP: Post-Exposure Prophylaxis

PHBPP: Perinatal Hepatitis B Prevention Program

PHR: Public Health Region

PIN: Provider Identification Number

PVST: Post-Vaccination Serologic Testing

RHC: Rural Health Clinic

SST: Serum Separator Tube

TAC: Texas Administrative Code

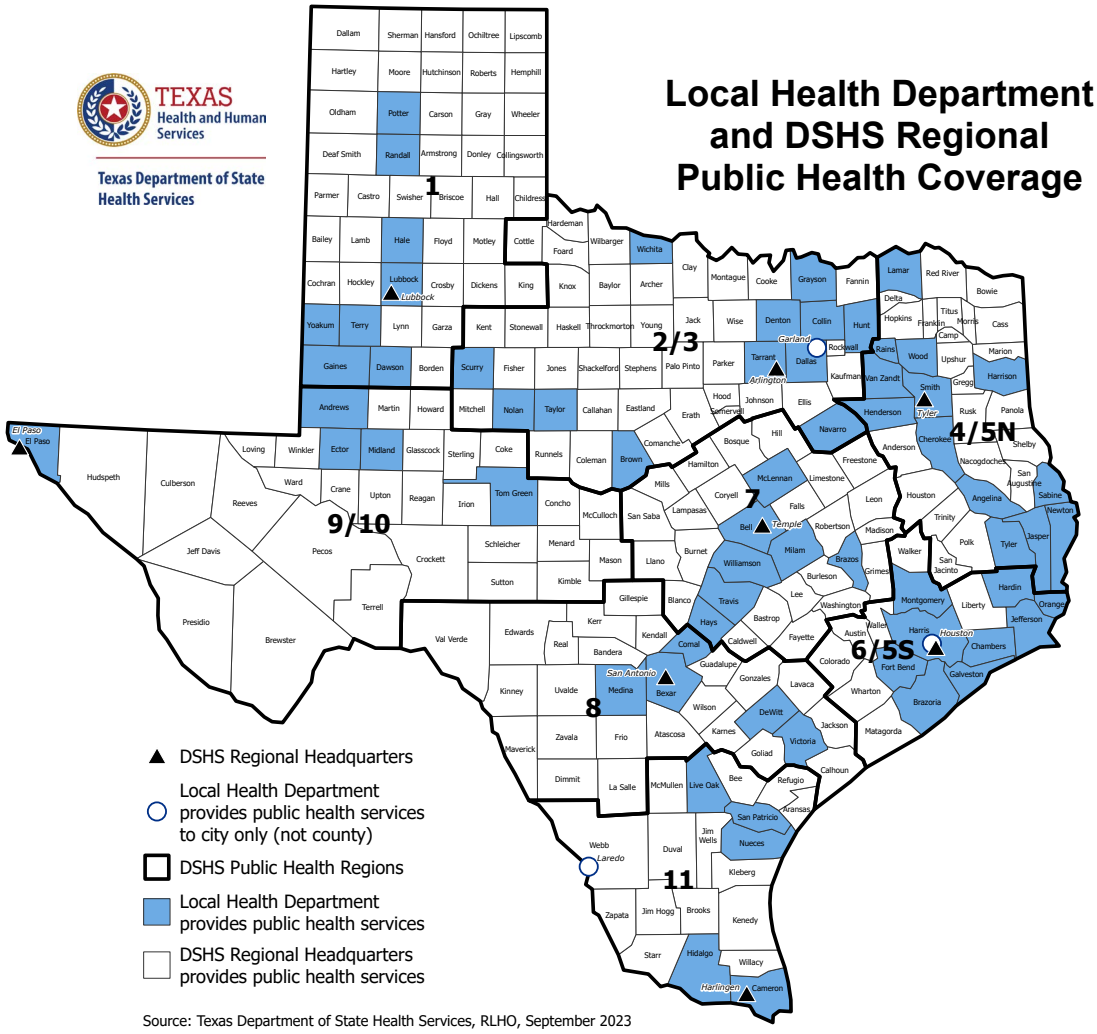
TVFC: Texas Vaccines for Children

WHO: World Health Organization

Perinatal Hepatitis B Virus Infection Case Definition

The case definition for perinatal hepatitis B virus infection is HBsAg positivity in an infant aged one to 24 months born in the United States (U.S.) or U.S. territories to an HBsAg-positive mother. An infant who is determined to be HBsAg-positive will be classified as a case of perinatal hepatitis B virus infection. Perinatal hepatitis B infection in the newborn may range from asymptomatic to fulminant hepatitis. All laboratory-confirmed perinatal hepatitis B virus infections must be reported to the Texas DSHS within one working day of notification.

Texas Program Regions

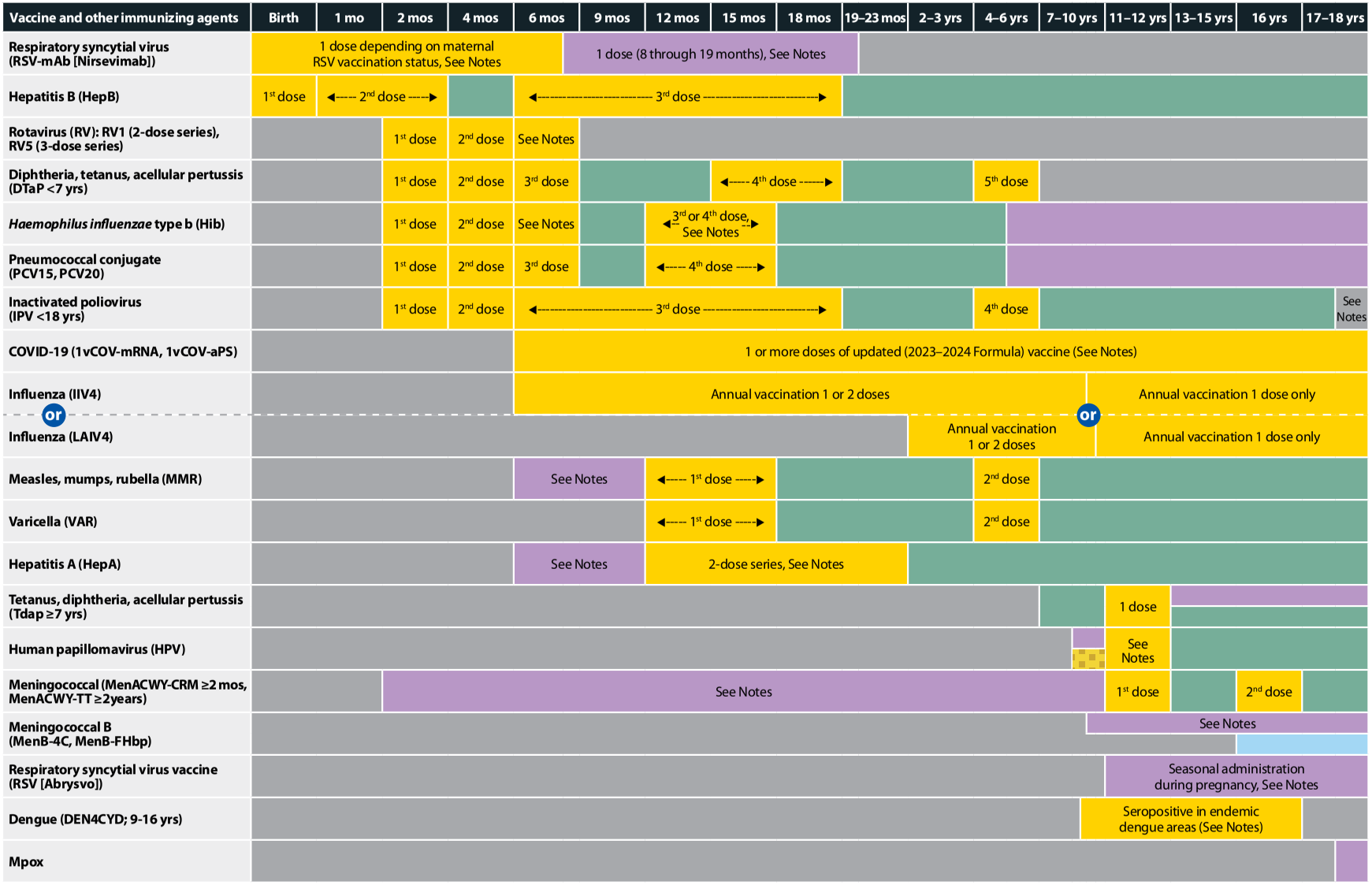


Source: Texas Department of State Health Services, RLHO, September 2023

Appendix B: Vaccine Schedule

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2024

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).



Give the Birth Dose...
Hepatitis B Vaccine at Birth Saves Lives!

■ By **Deborah L. Wexler, MD**
Executive Director, Immunization Action Coalition

In December 2005, CDC issued updated recommendations on hepatitis B vaccination for infants. The recommendations strongly support (1) giving the hepatitis B vaccine birth dose to every newborn prior to hospital discharge and (2) using standardized admission orders for administering the birth dose. In addition, it is recommended that a copy of the ***original*** *maternal hepatitis B lab report be sent to the hospital – **not** a transcribed result. The recommendations also state that the hepatitis B vaccine birth dose may be delayed until after hospital discharge only "in rare circumstances." When doing so, a physician's order to withhold the birth dose and a copy of the original lab report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record. The most recent CDC estimates indicate only 70% of newborns receive the hepatitis B vaccine birth dose by 3 days of age. Clearly, there is much work left to do to fully protect newborns.*

Healthcare professionals:
Urge your patients to protect their newborns with hepatitis B vaccine before hospital discharge.

Your recommendation to vaccinate is a strong patient motivator!

The birth dose saves lives!

To obtain CDC's recommendations for hepatitis B immunization of infants, children, and adolescents, visit www.cdc.gov/mmwr/pdf/rr/rr5416.pdf.

Leading health organizations – CDC, AAP, AAFP, and ACOG – recommend that all hospitals and healthcare professionals protect newborns from hepatitis B virus (HBV) infection by administering the first dose of hepatitis B vaccine to every baby at birth, no later than hospital discharge.

Approximately 24,000 women with chronic HBV infection give birth in the U.S. each year, and many do not know they are infected. Up to 95% of perinatal infections can be prevented by post-exposure prophylaxis given within 12 hours of birth. Tragically, many babies are exposed to HBV at birth and do not receive appropriate postexposure prophylaxis. Infants infected at birth have a 90% chance of becoming chronically infected with HBV. Chronic HBV infection in infants leads to liver cancer, cirrhosis, and liver failure in up to 25% of these infants when they become adults.

Why is a universal birth dose policy necessary in hospitals?

Following are some of the ways newborns can be infected if they do not receive a dose of hepatitis B vaccine, ideally within 12 hours of birth:

- The pregnant woman is tested and found to be hepatitis B surface antigen (HBsAg) positive, but her "infected" status is not communicated to the newborn nursery. The infant receives neither hepatitis B vaccine nor hepatitis B immune globulin (HBIG) protection at birth.

- A chronically infected pregnant woman receives the wrong test. For example, antibody to hepatitis B surface antigen (antiHBs) is ordered in error, instead of HBsAg. This can happen because some labs use the confusing abbreviation HBsAb instead of anti-HBs. This misordering of a test is relatively common since the two abbreviations (HBsAg and HBsAb) differ by only one letter. However, when her incorrectly ordered test comes back "negative," the woman may actually be HBsAg positive and her infant would not receive appropriate postexposure prophylaxis.
- The pregnant woman is HBsAg positive, but her test results are misinterpreted or mistranscribed into her prenatal record or her infant's chart. As a result, her infant does not receive HBIG or hepatitis B vaccine.

CONTINUED ON THE NEXT PAGE ▶

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www.immunize.org/catg.d/p2125.pdf • Item #P2125 (2/14)

- The pregnant woman is not tested for HBsAg either prenatally or in the hospital at the time of delivery. In one study, women who didn't receive prenatal care were eight times more likely to be HBsAg positive than women who received prenatal care. When a woman does not receive prenatal care and is not tested at the time of delivery, her infant is in danger of being infected with HBV at birth – unless he or she is born in a hospital that adheres to a policy of administering hepatitis B vaccine within 12–24 hours of birth to every newborn **without fail**. This provides the greatest effectiveness in preventing HBV infection.
- She develops HBV infection later in pregnancy, but it is not clinically detected. Because her initial HBsAg test result is negative, she is not retested later in pregnancy as CDC recommends for high-risk women, and her infant does not receive hepatitis B vaccine or HBIG at birth.
- The mother is HBsAg negative, but the infant is exposed to HBV postnatally from another family member or caregiver. This occurs in two-thirds of the cases of childhood transmission.

In 2001, 2002, and 2008, the Immunization Action Coalition surveyed perinatal hepatitis B coordinators at every state health department, as well as at city and county CDC projects to assess their views about providing hepatitis B vaccine in the hospital. Their responses contained hundreds of reports of newborns who were unprotected or inadequately protected because healthcare professionals failed to order or misordered hepatitis B blood tests or misinterpreted, mistranscribed, or miscommunicated the test results of the children's mothers. (See *States Report Hundreds of Medical Errors in Perinatal Hepatitis B Prevention*, at www.immunize.org/catg.d/p2062.pdf.)

These state coordinators' reports tell us that no matter how well healthcare providers think they are doing in screening all pregnant women for HBsAg, mistakes continue to occur. Newborns are unnecessarily being exposed without the benefit of postexposure prophylaxis. At least one baby has died of fulminant hepatitis B; hundreds have become chronically infected and are doomed to preventable hepatocellular carcinoma or cirrhosis later in life. To overcome these failures, perinatal hepatitis B vaccine coordinators overwhelmingly endorse providing a hepatitis B vaccine birth dose as the first step in developing a safety net to protect all infants from HBV infection, regardless of the circumstances.

To maximally protect every newborn, CDC, AAP, AAFP, and ACOG recommend all infants be vaccinated with a hepatitis B vaccine birth dose prior to hospital discharge. Delaying hepatitis B vaccination until a follow-up office visit will be too late to prevent perinatal HBV transmission.*

Hepatitis B vaccine is a highly effective vaccine. Studies have shown that infants of the most highly infectious mothers (women who are both HBsAg and HBeAg positive) who receive postexposure prophylaxis with hepatitis B vaccine alone (without HBIG) at birth are protected in 70%–95% of cases. Please read the hepatitis coordinators' survey results (www.immunize.org/birthdose/birthdose survey.asp), including descriptions of their experiences with failures of the system – failures that largely will be prevented by administering hepatitis B vaccine to infants before they go home from the hospital, ideally within 12 hours of birth.

Your support for providing a birth dose to newborns while they are still in the hospital will protect and save lives that are now being put at risk.

** For subsequent doses of hepatitis B vaccine in infants, use monovalent hepatitis B vaccine or hepatitis B-containing combination vaccines. If using a hepatitis B-containing combination vaccine, you will be giving 3 more doses of hepatitis B vaccine. Giving a total of 4 doses of hepatitis B vaccine to infants is acceptable practice according to CDC, AAP, and AAFP. These vaccine doses are covered under the Vaccines For Children (VFC) program for VFC-eligible children.*

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www.immunize.org/catg.d/p2125.pdf • Item #P2125 (2/14)

Dose	Recommended Age
One	Birth
Two	one-two months
Three	Six to 18 months*

Table B.2. Routine Infant Hepatitis B Vaccine Schedule Using Monovalent Vaccine

Both the ACIP and CDC recommend that all children born to women who are HBsAg-positive receive their final dose of the hepatitis B vaccine series at six months of age, as long as all minimum intervals (below) are met.

Pediarix ® Vaccine Schedule		
Biologic	Dose	Age of Infant
Hepatitis B Vaccine dose one	0.5 mL	Birth **(Monovalent vaccine only**)
Hepatitis B Vaccine dose two	0.5 mL	two months*
Hepatitis B Vaccine dose three	0.5 mL	four months
Hepatitis B Vaccine dose four	0.5 mL	six months**
*** Not approved for use in infants younger than six weeks of age. ** Final dose of vaccine should not be administered before six months (24 weeks) of age.**		

Table B.3. Infant Hepatitis B Vaccine Schedule Using Combination Vaccines

Minimum Dosing Intervals	
Dose one to two	Four weeks
Dose two to three	Eight weeks
Dose three	16 weeks after first dose*
*** Dose three <u>should not</u> be administered before six months (24 weeks) of age.**	

Table B.4. Minimum Dosing Intervals for Hepatitis B Vaccines

Guidance for Postexposure Prophylaxis (PEP) Treatment of Infants

Infant Born to an HBsAg–Positive mothers		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*±
Hepatitis B Vaccine dose one	0.5 mL	Within 12 hours of birth*±
Hepatitis B Vaccine dose two	0.5 mL	one month
Hepatitis B Vaccine dose three	0.5 mL	six months**
*** Administer at separate anatomical sites. Preferred site: anterolateral thighs.** **** Dose three should not be administered before six months (24 weeks) of age.** ± Regardless of infant's birth weight.		

Table B.5. PEP for Infants of HBsAg-Positive Mothers

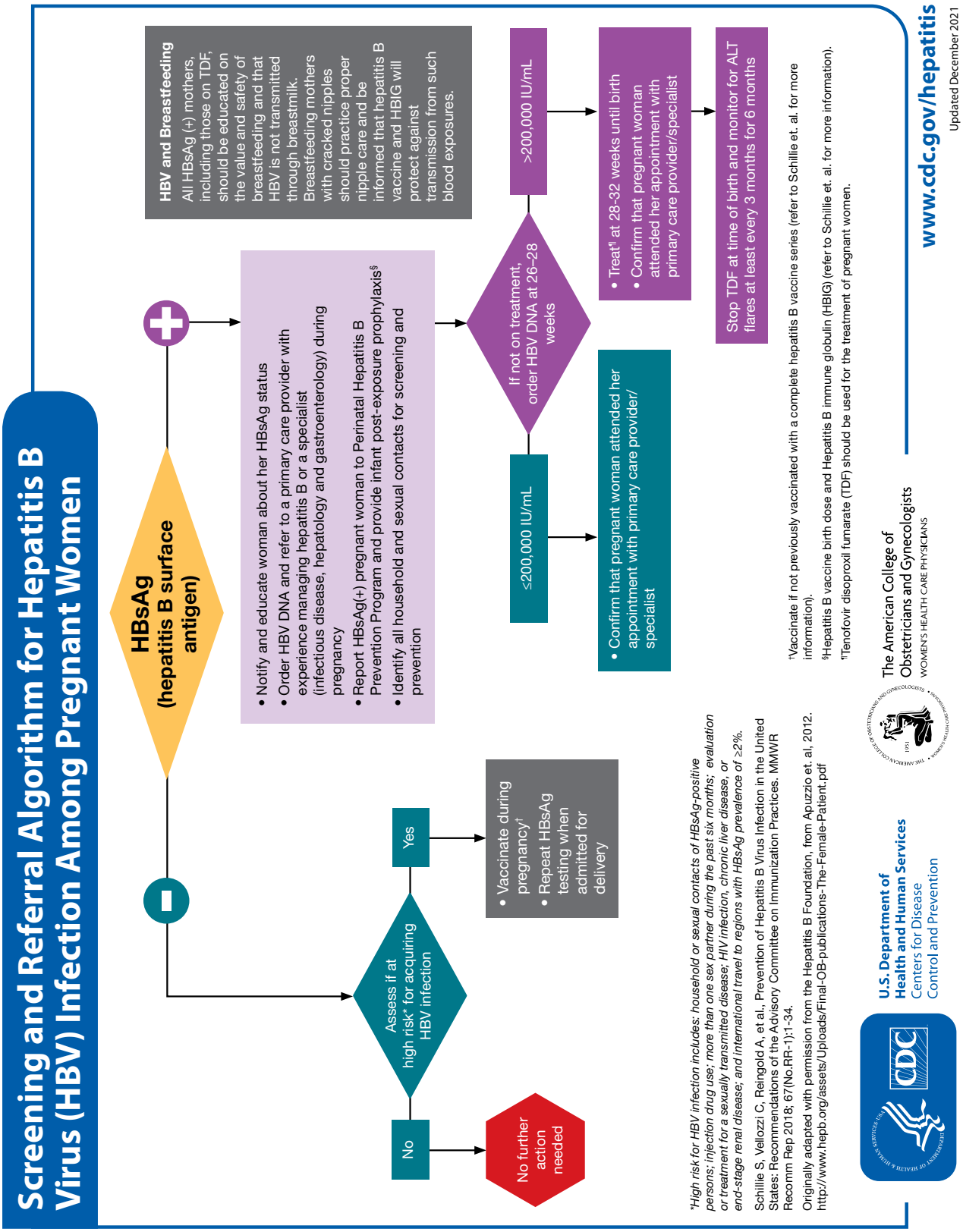
Infant Born to an HBsAg–Unknown Status mother±		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	If less than 2,000g - within 12 hours of birth*
		If 2,000g or greater – ASAP, but no later than seven days if mother is positive
Hepatitis B Vaccine dose one	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine dose two	0.5 mL	one to two months
Hepatitis B Vaccine dose three	0.5 mL	six months**
*** Administer at separate anatomical sites. Preferred site: anterolateral thigh** **** Dose three should not be administered before six months (24 weeks) of age.** **± In the event a mother's HBsAg status is initially unknown but her HBsAg delivery result comes back negative, the infant does not need to receive HBIG. However, it will not harm the infant if HBIG is administered before the result is received.**		

Table B.6. PEP for Infants of HBsAg-Unknown Mothers

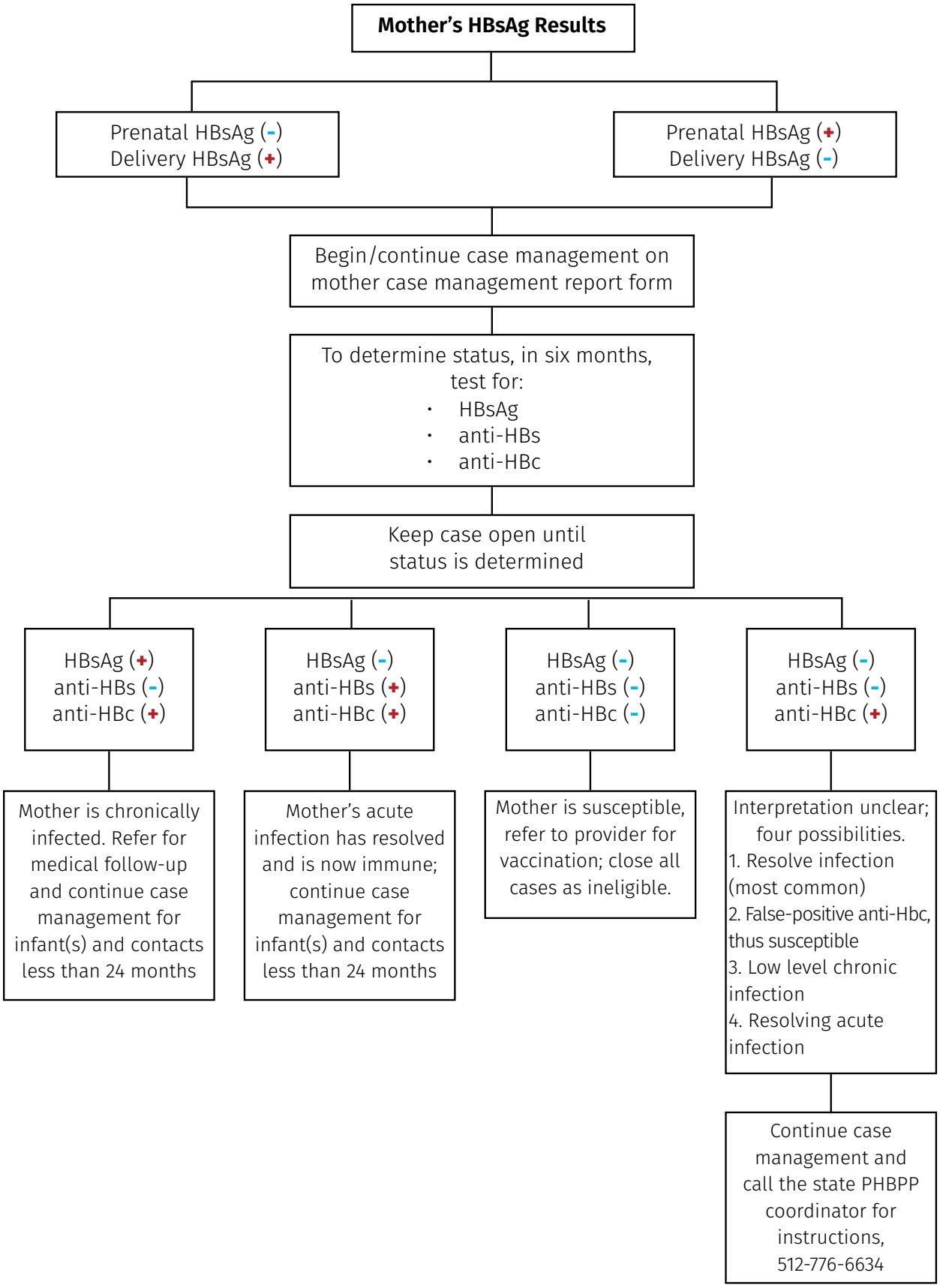
Infant Born to an HBsAg–Positive OR HBsAg-Unknown mother		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine dose one	0.5 mL	Within 12 hours of birth* **Do not count birth dose as part of series.**
Hepatitis B Vaccine dose 2	0.5 mL	one month
Hepatitis B Vaccine dose 3	0.5 mL	two months
Hepatitis B Vaccine dose four	0.5 mL	6 months**
*** Administer at separate anatomical sites. Preferred site: anterolateral thighs.** **** Dose three should not be administered before 6 months (24 weeks) of age.** **± All preterm infants weighing less than 2,000g at birth should reinitiate the series beginning at one month of age.**		

Table B.7. PEP of Infants Weighing less than 2,000g (4.4 lbs.)

Appendix C: Flowcharts and Diagrams

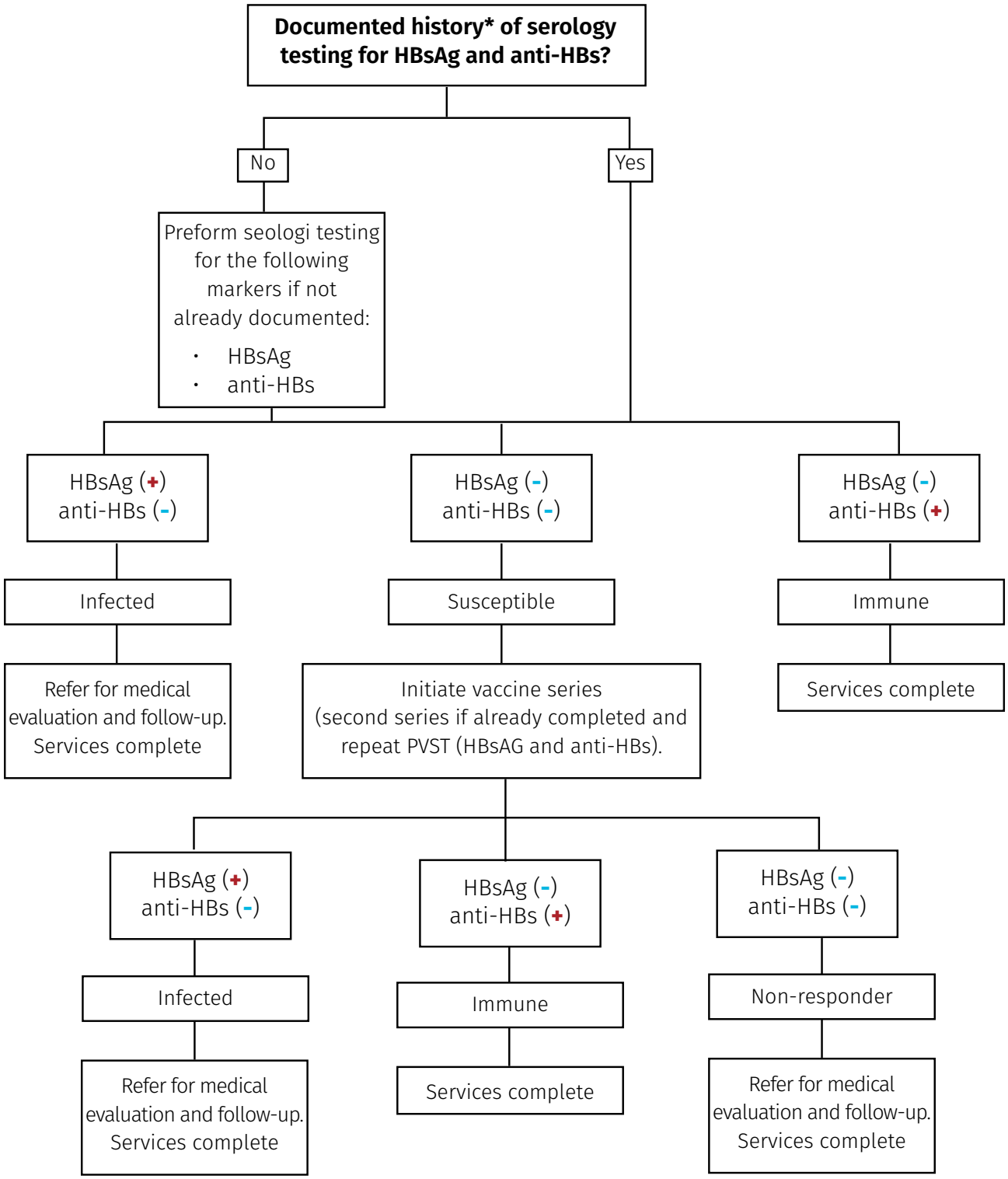


Guideline 1: Case Management of Mothers with Discrepant HBsAg Results



Guideline 2: Serology Testing and Case Management of Pregnant Women

Guideline 4: Follow-up for Contacts less than or equal to 24 months of age



*Serological testing history is defined as a written and dated laboratory report.

Appendix D Lab Ordering and Serology Interpretation

Hepatitis B Antigens and Markers

Hepatitis B DNA (HBV DNA)

HBV DNA is one of the first tests that can be detected in the bloodstream after initial infection. It can be detected as early as one week after infection. The amount of HBV DNA in the patient's blood indicates how fast the virus is replicating within the liver. This test measures the patient's viral load. High viral loads indicate rapid viral replication while low or undetectable levels indicate inactive infections. The CDC recommends all HBsAg positive pregnant women be tested for HBV DNA to guide antiviral therapy.

HBV-DNA Genotype

HBV DNA genotype testing identifies which of the genetic strains of hepatitis B virus a patient is infected with. It is most often used to predict or monitor therapy, detect mutations, or in epidemiologic investigations to assess transmission linkages.

Hepatitis B Surface Antigen (HBsAg)

HBsAg is found on the surface of the virus and can be identified approximately 30-60 days after exposure to the virus. The presence of HBsAg indicates that the person is infectious. HBsAg testing is the current standard to indicate current infection with hepatitis B. If HBsAg is present for more than six months this generally indicates a chronic infection.

Hepatitis B "little E" Antigen (HBeAg Or 'e' Antigen)

HBeAg is contained within the core of the virus rather than on the surface. When the virus replicates, HBeAg is produced in excess. The "little e" antigen is only detectable when the hepatitis B virus is actively reproducing. HBeAg indicates high infectivity due to the active replication of the virus and indicates a greater risk of progression to liver disease. HBeAg and HBsAg are generally detectable at the same time, however, HBeAg disappears before HBsAg. Mutant strains of HBV do exist that replicate without producing HBeAg. In many cases, infection with one of these mutant strains is more aggressive than HBe-producing strains.

Hepatitis B “little E” Antibody (anti-HBe)

Antibodies to HBeAg only become detectable when the HBeAg is no longer present, indicating there is no active viral replication. Serology that is anti-HBe positive would indicate low infectivity.

Hepatitis B Core Antigen (HBcAg)

The core antigen (HBcAg) is a viral protein that is produced and contained within the infected hepatocyte and is the most antigenic component of the virus. It does not freely circulate in a detectable amount within the blood, therefore, there is no specific lab test to detect the core antigen. However, it can be detected in a sample of liver cells taken after a liver biopsy. Because of the antigenicity of the core antigen, the immune system does produce antibodies to HBcAg (anti-HBc) that are detectable.

Hepatitis B Core Antibody (anti-HBc)

Anti-HBc positive serum indicates that the individual has been infected with the hepatitis B virus at some point, but it is not possible to determine when the infection occurred. Any individual who has been infected with the virus will test positive for anti-HBc for life.

Hepatitis B Immunoglobulin M (IgM Anti-HBc)

IgM anti-HBc is detectable approximately six to eight weeks after infection occurs and indicates acute infection. It is generally not detectable after six months and therefore generally indicates a recent infection. This is the best serologic marker of acute HBV infection.

Hepatitis B Surface Antibody (anti-HBs)

This is a protective antibody. The presence of anti-HBs following a known acute infection indicates recovery and immunity against reinfection. Anti-HBs can also be acquired as an immune response to the hepatitis B vaccine, indicating that the individual adequately responded to the vaccine and is protected from infection.

Screening Pregnant Women for Hepatitis B Virus (HBV) Infection:

Ordering Prenatal Hepatitis B Surface Antigen (HBsAg) Tests from Major Commercial Laboratories

Laboratory	Test Option	Test Name	Reflex to Confirmation Test*	Test Code/ID	CPT Code	Web Link
ARUP Laboratories	Panel	Prenatal Reflexive Panel	✓	0095044	87340**	http://ltd.aruplab.com/Tests/Pub/0095044
	Standalone	Hepatitis B Virus Surface Antigen with Reflex to Confirmation, Prenatal	✓	2007573	87340	http://ltd.aruplab.com/Tests/Pub/2007573
LabCorp	Panel	Prenatal Profile I with Hepatitis B Surface Antigen	✓	202945	80055	https://www.labcorp.com/wps/portal/provider/testmenu/ *(Enter test code or CPT code to search for test)*
	Panel	Hepatitis Profile XIII (HBV Prenatal Profile)	✓	265397	87340**	https://www.labcorp.com/wps/portal/provider/testmenu/ *(Enter test code or CPT code to search for test)*
	Standalone	N/A	N/A	N/A	N/A	
Mayo Medical Laboratories	Panel	Prenatal Hepatitis Evaluation	✓	PHSP	87340**	http://www.mayomedicallaboratories.com/test-catalog/Overview/5566
	Standalone	Hepatitis B Surface Antigen Prenatal, Serum	✓	HBAGP	87340	http://www.mayomedicallaboratories.com/test-catalog/Overview/86185
Quest Diagnostics	Panel	Obstetric Panel	✓	20210	80055	http://www.questdiagnostics.com/testcenter/BUOrderInfo.action?tc=20210&labCode=MIA
	Standalone	N/A	N/A	N/A	N/A	

**When an HBsAg test result is reactive, laboratories may automatically perform a confirmatory test without additional provider order.*

***This CPT code corresponds only to the HBsAg screening component of this laboratory panel; additional CPT codes might be associated with other component tests in this laboratory panel.*

Notes: CDC recommends healthcare providers use prenatal HBsAg tests (vs. non-specific tests) for pregnant women, which allows for reporting of positive results along with pregnancy status to public health jurisdictions. Refer all HBsAg positive pregnant women to Perinatal Hepatitis B Prevention Program coordinators for case management of mother and infant: http://www.cdc.gov/vaccines/vpd-vac/hepb/perinatal-contacts.htm.

Laboratories reserve the right to add, modify, or stop performing tests at any time – providers should review any test notifications from laboratories for changes.

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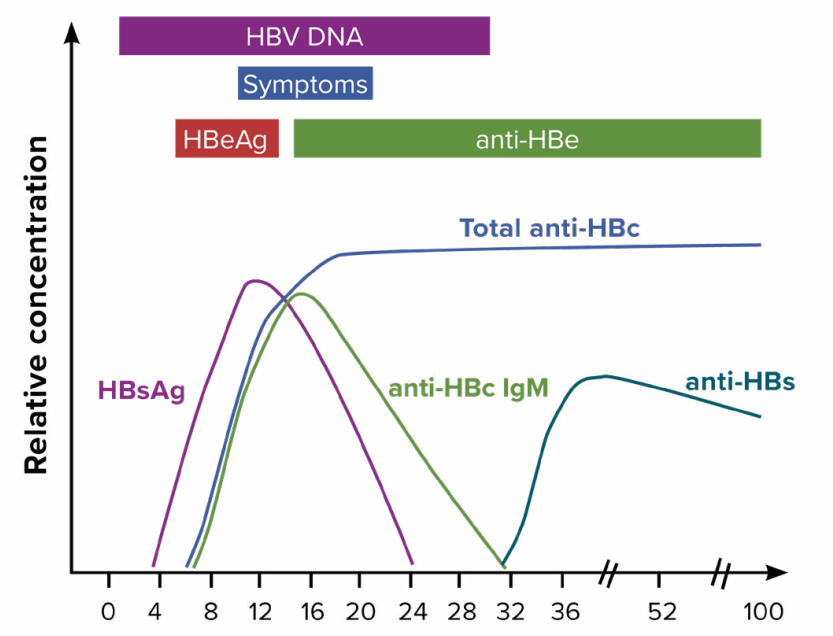

Figure D.1. Acute Hepatitis B Virus Infection with Recovery

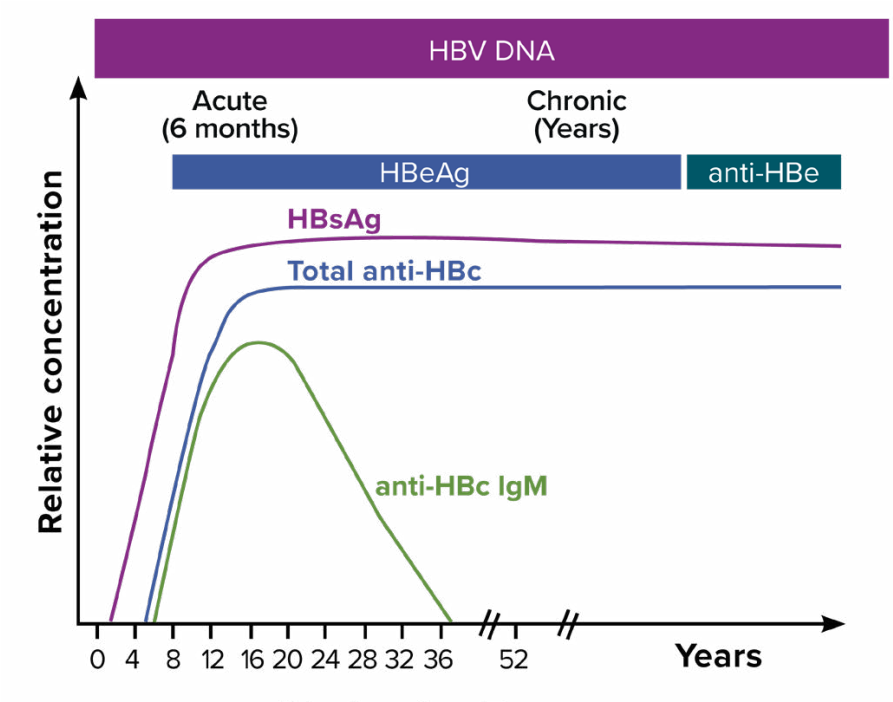

Figure D.2. Progression to Chronic Hepatitis B Virus Infection

HBsAg	Anti-HBs	Interpretation and Necessary Action
-	+	The infant is immune to HBV. Case management services are considered complete.
-	-	The infant is NOT immune to hepatitis B. The infant must receive a second dose of the hepatitis B vaccine as soon as post-vaccination serology results are known. The infant can then repeat PVST one-two months after the booster dose of the hepatitis B vaccine. If still not immune after the booster dose, the child should complete the 2nd and 3rd hepatitis B vaccine dose and repeat PVST one-two months later. Alternatively, providers and parents may decide to repeat the entire three-dose vaccine series and then repeat PVST one-two months later. See Chapter 5 for more detail.
+	-	The vaccination effort failed. The infant is infected with HBV (perinatal hepatitis B infection) and is likely to become a chronic carrier. All confirmed cases of perinatal HBV infection should be reported to the state through NEDSS as soon as they are identified, and to the perinatal hepatitis B coordinator through the submission of the ***Infant Case Management Form***, along with a copy of the laboratory report. Refer the child for clinical follow-up. Case management services are considered complete. **NOTE:** The surveillance case definition for perinatal hepatitis B virus infection is HBsAg positivity in any infant aged one-24 months or positive for HBeAg or HBV DNA aged 9-24 months who was born in the US or in US territories to an HBsAg-positive mother.

Table D.1. Interpretation of Infant Post-Vaccination Serologic Testing and Related Actions

Interpretation of Hepatitis B Serologic Test Results

Hepatitis B serologic testing involves measurement of several hepatitis B virus (HBV)-specific antigens and antibodies. Different serologic "markers" or combinations of markers are used to identify different phases of HBV infection and to determine whether a patient has acute or chronic HBV infection, is immune to HBV as a result of prior infection or vaccination, or is susceptible to infection.

HBsAg **anti-HBc** **anti-HBs**	negative negative negative	Susceptible
HBsAg **anti-HBc** **anti-HBs**	negative positive positive	Immune due to natural infection
HBsAg **anti-HBc** **anti-HBs**	negative negative positive	Immune due to hepatitis B vaccination
HBsAg **anti-HBc** **IgM anti-HBc** **anti-HBs**	positive positive positive negative	Acutely infected
HBsAg **anti-HBc** **IgM anti-HBc** **anti-HBs**	positive positive negative negative	Chronically infected
HBsAg **anti-HBc** **anti-HBs**	negative positive negative	Interpretation unclear; four possibilities: 1. Resolved infection (most common) 2. False-positive anti-HBc, thus susceptible 3. "Low level" chronic infection 4. Resolving acute infection

Adapted from: A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. Part I: Immunization of Infants, Children, and Adolescents. MMWR 2005;54(No. RR-16).

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- **Hepatitis B surface antigen (HBsAg):** A protein on the surface of hepatitis B virus; it can be detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make hepatitis B vaccine.
- **Hepatitis B surface antibody (anti-HBs):** The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.
- **Total hepatitis B core antibody (anti-HBc):** Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.
- **IgM antibody to hepatitis B core antigen (IgM anti-HBc):** Positivity indicates recent infection with hepatitis B virus (≤6 mos). Its presence indicates acute infection.

Recommendations for Routine Testing and Follow-up for Chronic Hepatitis B Virus (HBV) Infection

Population	Recommendation	
	Testing	Vaccination/Follow-up
Persons born in regions of high and intermediate HBV endemicity (HBsAg prevalence ≥2%)	Test for HBsAg, regardless of vaccination status in their country of origin, including – immigrants – refugees – asylum seekers – internationally adopted children	If HBsAg-positive, refer for medical management. If negative, assess for on-going risk for hepatitis B and vaccinate if indicated.
US born persons not vaccinated as infants whose parents were born in regions with high HBV endemicity (≥8%)	Test for HBsAg regardless of maternal HBsAg status if not vaccinated as infants in the United States.	If HBsAg-positive, refer for medical management. If negative, assess for on-going risk for hepatitis B and vaccinate if indicated.

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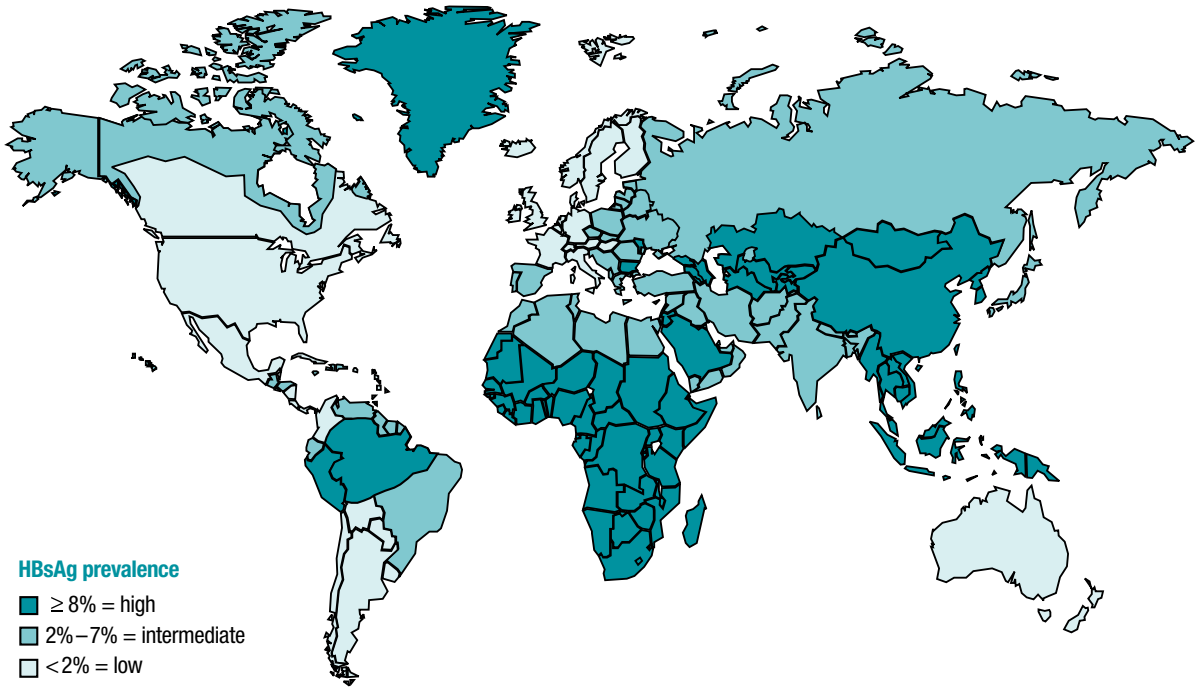
Geographic Distribution of Chronic HBV Infection — Worldwide, 2006*



* For multiple countries, estimates of prevalence of hepatitis B surface antigen (HBsAg), a marker of chronic HBV infection, are based on limited data and might not reflect current prevalence in countries that have implemented childhood hepatitis B vaccination. In addition, HBsAg prevalence might vary within countries by subpopulation and locality.

Source: CDC. Travellers' Health; Yellow Book. http://wwwn.cdc.gov/travel/yellowbookch4-HepB.aspx.

Routine Testing and Follow-up for Chronic HBV Infection (continued)

Population	Recommendation	
	Testing	Vaccination/Follow-up
Injection-drug users	Test for HBsAg, as well as for anti-HBc or anti-HBs to identify susceptible persons.	First vaccine dose should be given at the same visit as testing. Susceptible persons should complete a 3-dose hepatitis B vaccine series to prevent infection from ongoing exposure.
Men who have sex with men	Test for HBsAg, as well as for anti-HBc or anti-HBs to identify susceptible persons.	First vaccine dose should be given at the same visit as testing. Susceptible persons should complete a 3-dose hepatitis B vaccine series to prevent infection from ongoing exposure.
Persons needing immunosuppressive therapy, including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatologic or gastroenterologic disorders	Test for all markers of HBV infection (HBsAg, anti-HBc, and anti-HBs).	Treat persons who are HBsAg-positive. Monitor closely persons who are anti-HBc positive for signs of liver disease.
Persons with elevated ALT/AST of unknown etiology	Test for HBsAg along with other appropriate medical evaluation.	Follow-up as indicated.
Donors of blood, plasma, organs, tissues, or semen	Test for HBsAg, anti-HBc, and HBV-DNA as required.	
Hemodialysis patients	Test for all markers of HBV infection (HBsAg, anti-HBc, and anti-HBs). Test vaccine nonresponders monthly for HBsAg. HBsAg-positive hemodialysis patients should be cohorted.	Vaccinate against hepatitis B to prevent transmission and revaccinate when serum anti-HBs titer falls below 10mIU/mL.
All pregnant women	Test for HBsAg during each pregnancy, preferably in the first trimester. Test at the time of admission for delivery if prenatal HBsAg test result is not available or if mother was at risk for infection during pregnancy.	If HBsAg-positive, refer for medical management. To prevent perinatal transmission, infants of HBsAg-positive mothers and unknown HBsAg status mothers should receive vaccination and postexposure immunoprophylaxis in accordance with recommendations and within 12 hours of delivery.
Infants born to HBsAg-positive mothers	Test for HBsAg and anti-HBs 1–2 mos after completion of at least 3 doses of a licensed hepatitis B vaccine series (i.e., at age 9–18 months, generally at the next well-child visit to assess effectiveness of postexposure immunoprophylaxis). Testing should not be performed before age 9 months or within 1 month of the most recent vaccine dose.	Vaccinate in accordance with recommendations.
Household, needle-sharing, or sex contacts of persons known to be HBsAg positive	Test for HBsAg, as well as anti-HBc or anti-HBs to identify susceptible persons.	First vaccine dose should be given at the same visit as testing. Susceptible persons should complete a 3-dose hepatitis B vaccine series to prevent transmission from ongoing exposure.
Persons who are the sources of blood or body fluids resulting in an exposure (e.g., needlestick, sexual assault) that might require postexposure prophylaxis	Test source for HBsAg.	Vaccinate healthcare and public safety workers with reasonably anticipated occupational exposures to blood or infectious body fluids. Provide postexposure prophylaxis to exposed person if needed.
HIV-positive persons	Test for HBsAg, as well as for anti-HBc or anti-HBs to identify susceptible persons.	Vaccinate susceptible persons against hepatitis B to prevent transmission.

Adapted from: Centers for Disease Control and Prevention. Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection. MMWR 2008; 57 (No. RR-8).

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Appendix E: Policies, Standing Orders, and HIPAA

Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission

The guidelines in this document were developed to help hospitals establish policies and standing orders in their labor and delivery (L&D) and newborn units.

In January 2018, CDC published revised guidance to administer the hepatitis B birth dose within 24 hours of birth to all newborns. This and other current hepatitis B recommendations are available at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf.

To protect infants from HBV infection, CDC recommends that all delivery hospitals institute standing orders or admission orders, and protocols to ensure healthcare professionals do the following:

1. Administer hepatitis B vaccine to **ALL newborns** within 24 hours of birth, or at hospital discharge, whichever comes first.
2. Identify all infants born to mothers who are hepatitis B surface antigen (HBsAg) positive or to mothers with unknown HBsAg status. Administer appropriate immunoprophylaxis to these infants.

Admission orders and procedures for pregnant people admitted to a birthing facility

For pregnant people who have a HBsAg lab report included in their prenatal records, do the following:

1. Examine a copy of the *original* laboratory report of the pregnant person's HBsAg[1] test result to verify that the correct test (i.e., HBsAg) was performed and to verify that the testing date was during *this* pregnancy not a previous one. *Do not rely on a handwritten or transcribed HBsAg test result!*
2. Place a copy of the original HBsAg lab report into (1) the pregnant person's L&D record and (2) the infant's hospital record (or have a link to the mother's HBsAg test result).
3. If the pregnant person is HBsAg positive, alert the nursery staff that the newborn is high risk and will need postexposure prophylaxis – both hepatitis B immune globulin (HBIG) and hepatitis B vaccine – within 12 hours of birth.
4. Perform a repeat blood test for HBsAg[1] if the pregnant person was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner), or had clinical hepatitis since the previous test.
5. Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

For pregnant people who do not have an HBsAg lab report on their prenatal record, do the following:

1. Perform HBsAg[1] testing ASAP on people who do not have a copy of an original HBsAg laboratory report from the current pregnancy included in their prenatal record.
2. Instruct the lab to call L&D and the nursery units with the newly obtained HBsAg test result ASAP.

Admission orders and procedures for newborns

Hospital procedures to follow for ALL newborns

1. Review a copy of the mother's *original* HBsAg[1] lab report to ensure that the correct serologic test was ordered and that it was ordered during this pregnancy.
2. Determine if the newborn needs immediate postexposure prophylaxis within 12 hours of birth. To do this you must know the mother's HBsAg status and the newborn's birth weight. If the newborn weighs less than 2 kg (4.4 lb), see the descriptions below and footnotes 2, 4, 5.
3. Prior to vaccination, give parent a Hepatitis B Vaccine Information Statement (available at www.immunize.org/vis).
4. If an infant is transferred to a higher level of care facility prior to vaccination, inform the receiving facility it is their responsibility to administer the hepatitis B vaccine.

For newborns of HBsAg-negative mothers

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 24 hours of birth, or at hospital discharge, whichever comes first, to **all** newborns weighing 2 kg (4.4 lb) or more at birth.[2, 3]
2. Document the hepatitis B vaccine dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the importance of completing the hepatitis B vaccine series to protect the baby. Remind the mother to bring the immunization record card each time the baby sees a provider.

For newborns of mothers with unknown HBsAg status,[6] do the following:

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.[3, 4] Do not wait for test results to return before giving this dose of vaccine.
2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, and site of administration, as well as the vaccine lot number.

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3 Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the importance of completing the hepatitis B vaccine series to protect the baby. Remind the mother to bring the immunization record card each time the baby sees a provider.

4 Confirm that the laboratory has received blood for the mother's HBsAg[1] test.

5 Verify when the mother's HBsAg result will be available and that it will be reported to L&D and the newborn unit ASAP.

6 If the nursery does not receive the report of the mother's HBsAg test at the expected time, call the laboratory for the result.

7 If the laboratory test indicates the mother's HBsAg[1] test result is positive, do the following:
- **a** Administer HBIG (0.5 mL, IM) to the newborn ASAP. (Hepatitis B vaccine should have been given within 12 hours of birth.)
- **b** Document the HBIG dose in the newborn's medical record. There is little benefit in administering HBIG to the newborn if more than 7 days have elapsed since birth.
- **c** Alert the mother's and newborn's physician(s) of the test result.
- **d** Follow the instructions below "For newborns of HBsAg-positive mothers," steps 3–7.

8 If the newborn must be discharged before the mother's HBsAg result is known:
- **a** Document the parents' contact information (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed for the infant.
- **b** Obtain the name, address, and phone number of the mother's and the newborn's healthcare providers.
- **c** Notify the mother's and newborn's healthcare providers that the mother's HBsAg test result is pending.

For newborns of HBsAg-positive mothers

1 Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine[3, 5] (0.5 mL, IM) at separate injection sites within 12 hours of birth.

2 Document the hepatitis B vaccine and HBIG dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.

3 Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates. Explain the importance of completing the hepatitis B vaccine series to protect the baby. Remind the mother to bring the record card each time the baby sees a provider.

4 Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.

5 Obtain the name, address, and phone number of the newborn's primary care provider.

6 Notify the provider of the newborn's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination as well as postvaccination testing of the infant for both HBsAg and antibody to HBsAg (anti-HBs) after completion of the hepatitis B vaccine series to assess the hepatitis B status of the infant following vaccination.

7 Provide advice to the mother. Explain the following:
- **a** That the mother may breast-feed the infant upon delivery, even before hepatitis B vaccine and HBIG are given;
- **b** That it is critically important for the protection of her baby's health that the baby receives the full hepatitis B vaccine series on the recommended schedule;
- **c** That blood tests (HBsAg and antibody to hepatitis B surface antigen [anti-HBs]) need to be drawn from the baby 1–2 months after completion of the 3- or 4-dose hepatitis B vaccine series and also no earlier than 9–12 months of age to determine if the child developed a protective immune response to vaccination or needs additional management;[7]
- **d** About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
- **e** That the mother needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether the mother is a candidate for antiviral treatment.

FOOTNOTES

1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was/is ordered. The HBsAg test should not be confused with other hepatitis B serologic tests, including antibody to HBsAg (anti-HBs or HBsAb) and antibody to hepatitis B core antigen (anti-HBc or HBcAb).
2. Infants weighing less than 2 kg (4.4 lb) at birth and whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge, whichever comes first. The mother's HBsAg test result must be part of the infant's medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download it from the Immunize.org website at www.immunize.org/vis.
4. An infant weighing less than 2 kg (4.4 lb) whose mother's HBsAg status is unknown should receive HBIG and hepatitis B vaccine within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
5. An infant weighing less than 2 kg (4.4 lb) whose mother is HBsAg positive should receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
6. If it is not possible to determine the mother's HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers. The final dose in the series should not be administered before age 24 weeks (164 days). These infants should receive postvacci nation serologic testing at age 9–12 months, and revaccination if necessary.
7. The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be transiently positive for 1–18 days after vaccination. Serologic testing should be performed no earlier than age 9 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection (see "Update: Shortened interval for postvaccination serologic testing of infants born to hepatitis B-infected mothers," *MMWR*, 2015;64: 1118–20 at www.cdc.gov/mmwr/pdf/wk/mm6439.pdf).

▶ ***For "Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Birth Dose," visit www.immunize.org/catg.d/p2131.pdf.***

Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Vaccine Birth Dose

Routine orders for all newborns

1. Review a copy of the mother's original lab report to ensure that the correct serologic test (HBsAg) was ordered and that it was ordered during this pregnancy. Perform a repeat HBsAg blood test on the pregnant person (mother) if the mother was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner), or had clinical hepatitis since her previous testing.
2. Determine if the newborn is high risk and needs immediate postexposure prophylaxis within 12 hours of birth. The infant is high risk if the mother's HBsAg status is positive or unknown.

For routine hepatitis B vaccination of normal weight infants: the mother is HBsAg negative

1. Administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, intramuscular (IM), in anterolateral thigh within 24 hours of birth (or sooner if the infant is discharged before 24 hours). Prior to vaccination, give the parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. Give the parent a record of the vaccination. If parent is unwilling to give consent, notify physician ASAP. Document vaccine administration or vaccine refusal in hospital record.

NOTE: For infants weighing less than 2 kg (4.4 lbs.), administer the vaccine at hospital discharge or by 1 month of age, whichever comes first.

For highest-risk infants: the mother is HBsAg positive

1. Administer Hepatitis B Immune Globulin (HBIG) 0.5 mL, IM, in anterolateral thigh in the delivery room or ASAP within 12 hours of birth. Document HBIG administration in hospital record. Give parent a record of the HBIG dose.

2. At same time and in opposite anterolateral thigh, administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, IM, ASAP within 12 hours of birth. Document vaccine administration in hospital record. Give parent a record of the vaccination.
3. Prior to administering both HBIG and hepatitis B vaccine, give parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. If parent unwilling to give consent, notify physician ASAP. Consider notifying Child Protective Services if parent continues to refuse despite discussion with physician.

4. Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
5. Obtain the name, address, and phone number of the newborn's primary care provider.

6. Notify primary care provider of newborn's birth, the date and time that HBIG and hepatitis B vaccine doses were administered, and the importance of additional on-time vaccination (infants weighing less than 2 kg (4.4 lbs) will require 4 doses of vaccine as the first dose does not "count") and postvaccination testing of the infant for HBsAg and antiHBs (antibody to HBsAg) 1–2 months after completion of the hepatitis B vaccine series and no earlier than when the infant is 9–12 months of age.

NOTE: The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be transiently positive for 1–18 days after vaccination. Serologic testing should be performed no earlier than age 9 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection.

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7 Provide advice to the mother. Explain the following:
   - **a** That the mother may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
   - **b** It is critical for the infant to complete the full hepatitis B vaccine series on the recommended schedule;
   - **c** Blood tests (HBsAg and anti-HBs) will need to be obtained from the infant 1–2 months after completion of the hepatitis B vaccine series (at 9–12 months of age) to determine if the infant developed a protective immune response to vaccination or needs additional management;
   - **d** About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
   - **e** The mother and other infected contacts need to have medical evaluations for chronic hepatitis B, including assessment to determine if they are candidates for antiviral treatment.

For high-risk infants: the mother's HBsAg status is unknown*

1 Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth. For infants weighing less than 2 kg (4.4 lbs) at birth, also administer hepatitis B immune globulin (HBIG 0.5 mL, IM) within 12 hours. Do not wait for test results to return before giving this dose of vaccine (and HBIG for infants weighing less than 2 kg [4.4 lb]). Document vaccine administration in the hospital record. Give the parent a record of the vaccination.

2 Confirm that the laboratory has received blood for the mother's HBsAg test.

3 Verify when the mother's HBsAg result will be available and that it will be reported to the newborn unit ASAP.

4 If the laboratory test indicates the mother's HBsAg test result is positive, do the following:
   - **a** Administer HBIG 0.5 mL, IM, ASAP to the newborn weighing 2 kg (4.4 lb) or more. (Those weighing less than 2 kg (4.4 lb) at birth should have already received HBIG.) (Hepatitis B vaccine should have been given within 12 hours of birth to all infants of mothers with unknown HBsAg status.)
   - **b** Follow steps 4–7 of the previous section (see "For highest-risk infants: the mother is HBsAg positive").

*If it is not possible to determine the mother's HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers. The final dose in the series should not be administered before age 24 weeks (164 days). These infants should receive post-vaccination serologic testing at age 9–12 months, and revaccination if necessary.

REFERENCE

CDC. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR, January 12, 2018;67(RR-1):1-30, available at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf.

▶ **For additional detailed information about text that you might incorporate into newborn admission orders, including orders for premature infants, refer to *Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission* available at www.immunize.org/catg.d/p2130.pdf.**

§ 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) Where provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to a business associate.

(c) To the extent required under the Social Security Act, 42 U.S.C. 1320a-7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 78 FR 5687, Jan. 25, 2013]

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

Administrative simplification provision means any requirement or prohibition established by:

(1) 42 U.S.C. 1320d-1320d-4, 1320d-7, 1320d-8, and 1320d-9;

(2) Section 264 of Pub. L. 104-191;

(3) Sections 13400-13424 of Public Law 111-5; or

(4) This subchapter.

ALJ means Administrative Law Judge.

ANSI stands for the American National Standards Institute.

Business associate: (1) Except as provided in paragraph (4) of this definition, business associate means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in this section) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this subchapter, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity may be a business associate of another covered entity.

(3) *Business associate* includes:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(4) *Business associate* does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance

this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(iv) Section 164.504 relating to the organizational requirements for covered entities;

(v) Section 164.512 relating to uses and disclosures for which individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) Where provided, the standards, requirements, and implementation specifications adopted under this subpart apply to a business associate with respect to the protected health information of a covered entity.

(d) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 78 FR 5695, Jan. 25, 2013]

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons held in lawful custody* includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term *record* means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Health care operations means any of the following activities of the covered entity to the extent that the

activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Except as prohibited under § 164.502(a)(5)(i), underwriting, enrollment, premium rating, and other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Inmate means a person incarcerated in or otherwise confined to a correctional institution.

Marketing: (1) Except as provided in paragraph (2) of this definition, marketing means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) Marketing does not include a communication made:

(i) To provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the covered entity in exchange for making the communication is

reasonably related to the covered entity's cost of making the communication.

(ii) For the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication:

(A) For treatment of an individual by a health care provider, including case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual;

(B) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; or

(C) For case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment.

(3) *Financial remuneration* means direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.

Payment means:

(1) The activities undertaken by:

(i) Except as prohibited under § 164.502(a)(5)(i), a health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 74 FR 42769, Aug. 24, 2009; 78 FR 5695, Jan. 25, 2013]

§ 164.502 Uses and disclosures of protected health information: General rules.

(a) *Standard.* A covered entity or business associate may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Covered entities: Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of §§ 164.502(b), 164.514(d), and 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Except for uses and disclosures prohibited under § 164.502(a)(5)(i), pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, § 164.514(e), (f), or (g).

(2) *Covered entities: Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subchapter.

(3) *Business associates: Permitted uses and disclosures.* A business associate may use or disclose protected health information only as permitted or required by its business associate contract or other arrangement pursuant to § 164.504(e) or as required by law. The business associate may not use or disclose protected health information in a manner that would violate the requirements of this subpart, if done by the covered entity, except for the purposes specified under § 164.504(e)(2)(i)(A) or (B) if such uses or disclosures are permitted by its contract or other arrangement.

(4) *Business associates: Required uses and disclosures.* A business associate is required to disclose protected health information:

(i) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the business associate's compliance with this subchapter.

(ii) To the covered entity, individual, or individual's designee, as necessary to satisfy a covered entity's obligations under § 164.524(c)(2)(ii) and (3)(ii) with respect to an individual's request for an electronic copy of protected health information.

(5) *Prohibited uses and disclosures.*

(i) *Use and disclosure of genetic information for underwriting purposes:* Notwithstanding any other provision of this subpart, a health plan, excluding an issuer of a long-term care policy falling within paragraph (1)(viii) of the definition of *health plan,* shall not use or disclose protected health information that is genetic information for underwriting purposes. For purposes of paragraph (a)(5)(i) of this section, underwriting purposes means, with respect to a health plan:

(A) Except as provided in paragraph (a)(5)(i)(B) of this section:

(*1*) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(*2*) The computation of premium or contribution amounts under the plan, coverage, or policy (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(*3*) The application of any pre-existing condition exclusion under the plan, coverage, or policy; and

§ 164.504 Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section:

Plan administration functions means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

Summary health information means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at § 164.514(b)(2)(i) has been deleted, except that the geographic information described in § 164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

(b)-(d) [Reserved]

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2), (e)(3), or (e)(5) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in § 164.502(e) and this paragraph, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(iii) A business associate is not in compliance with the standards in § 164.502(e) and this paragraph, if the business associate knew of a pattern of activity or practice of a subcontractor that constituted a material breach or violation of the subcontractor's obligation under the contract or other arrangement, unless the business associate took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of protected health information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards and comply, where applicable, with subpart C of this part with respect to electronic protected health information, to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware, including breaches of unsecured protected health information as required by § 164.410;

(D) In accordance with § 164.502(e)(1)(ii), ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) To the extent the business associate is to carry out a covered entity's obligation under this subpart, comply with the requirements of this subpart that apply to the covered entity in the performance of such obligation.

(I) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(J) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with this paragraph and § 164.314(a)(1), if applicable, by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section and § 164.314(a)(2), if applicable.

(B) The covered entity may comply with this paragraph and § 164.314(a)(1), if applicable, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section and § 164.314(a)(2), if applicable.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate in § 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph and § 164.314(a)(1), if applicable, provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(2) of this section and § 164.314(a)(1), if applicable, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(iv) A covered entity may comply with this paragraph and § 164.314(a)(1) if the covered entity discloses only a limited data set to a business associate for the business associate to carry out a health care operations function and the covered entity has a data use agreement with the business associate that complies with § 164.514(e)(4) and § 164.314(a)(1), if applicable.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the protected health information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the protected health information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(*1*) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person; and

(*2*) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(5) *Implementation specifications: Business associate contracts with subcontractors.* The requirements of § 164.504(e)(2) through (e)(4) apply to the contract or other arrangement required by § 164.502(e)(1)(ii) between a business associate and a business associate that is a subcontractor in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

(ii) Except as prohibited by § 164.502(a)(5)(i), the group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for purposes of:

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.

(3) *Implementation specifications: Uses and disclosures.* A group health plan may:

(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by § 164.520(b)(1)(iii)(C) is included in the appropriate notice; and

(iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

(g) *Standard: Requirements for a covered entity with multiple covered functions.*

(1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.

(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 78 FR 5697, Jan. 25, 2013]

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) through (4) or that are prohibited under § 164.502(a)(5)(i), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.*

(1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) *Implementation specifications: Treatment, payment, or health care operations.* (1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to other participants in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and

(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.

(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.

(b) *Standard: Uses and disclosures for involvement in the individual's care and notification purposes*

(1) *Permitted uses and disclosures.*

(i) A covered entity may, in accordance with paragraphs (b)(2), (b)(3), or (b)(5) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's health care or payment related to the individual's health care.

(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section, as applicable.

(2) *Uses and disclosures with the individual present.* If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based on the exercise of professional judgment, that the individual does not object to the disclosure.

(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's care or payment related to the individual's health care or needed for notification purposes. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

(4) *Uses and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of this section apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

(5) *Uses and disclosures when the individual is deceased.* If the individual is deceased, a covered entity may disclose to a family member, or other persons identified in paragraph (b)(1) of this section who were involved in the individual's care or payment for health care prior to the individual's death, protected health information of the individual that is relevant to such person's involvement, unless doing so is inconsistent with any prior expressed preference of the individual that is known to the covered entity.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002; 78 FR 5699, Jan. 25, 2013]

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure

permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.*

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: Uses and disclosures for public health activities.* (1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who provides health care to the individual at the request of the employer:

(*1*) To conduct an evaluation relating to medical surveillance of the workplace; or

(*2*) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(*1*) By giving a copy of the notice to the individual at the time the health care is provided; or

(*2*) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(vi) A school, about an individual who is a student or prospective student of the school, if:

(A) The protected health information that is disclosed is limited to proof of immunization;

(B) The school is required by State or other law to have such proof of immunization prior to admitting the individual; and

(C) The covered entity obtains and documents the agreement to the disclosure from either:

(1) A parent, guardian, or other person acting *in loco parentis* of the individual, if the individual is an unemancipated minor; or

(2) The individual, if the individual is an adult or emancipated minor.

(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

(c) *Standard: Disclosures about victims of abuse, neglect or domestic violence*

(1) *Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:

(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(d) *Standard: Uses and disclosures for health oversight activities*

(1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) *Joint activities or investigations.* Nothwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

(4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

(e) *Standard: Disclosures for judicial and administrative proceedings*

(1) *Permitted disclosures.* A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or

(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:

(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or

(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);

(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and

(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:

(*1*) No objections were filed; or

(*2*) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information , if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a *qualified protective order* means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

(vi) Nothwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(iv) of this section.

(2) *Other uses and disclosures under this section.* The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.

(f) *Standard: Disclosures for law enforcement purposes.* A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) *Permitted disclosures: Pursuant to process and as otherwise required by law.* A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(*1*) The information sought is relevant and material to a legitimate law enforcement inquiry;

(*2*) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(*3*) De-identified information could not reasonably be used.

(2) *Permitted disclosures: Limited information for identification and location purposes.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

(i) The covered entity may disclose only the following information:

(A) Name and address;

(B) Date and place of birth;

(C) Social security number;

(D) ABO blood type and rh factor;

(E) Type of injury;

(F) Date and time of treatment;

(G) Date and time of death, if applicable; and

(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:

(i) The individual agrees to the disclosure; or

(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:

(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;

(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and

(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.

(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith

constitutes evidence of criminal conduct that occurred on the premises of the covered entity.

(6) *Permitted disclosure: Reporting crime in emergencies.*

(i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:

(A) The commission and nature of a crime;

(B) The location of such crime or of the victim(s) of such crime; and

(C) The identity, description, and location of the perpetrator of such crime.

(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.

(g) *Standard: Uses and disclosures about decedents.*

(1) *Coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.

(2) *Funeral directors.* A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral directors to carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.

(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

(i) *Standard: Uses and disclosures for research purposes*

(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by § 164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(*1*) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(*2*) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(*3*) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(*1*) An adequate plan to protect the identifiers from improper use and disclosure;

(*2*) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(*3*) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the institutional review board or privacy board, pursuant to paragraph (i)(2)(ii)(C) of this section;

(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;

(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

(j) *Standard: Uses and disclosures to avert a serious threat to health or safety*

(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or

(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:

(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or

(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.

(2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:

(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or

(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.

(3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.

(4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

(k) *Standard: Uses and disclosures for specialized government functions.*

(1) *Military and veterans activities*

(i) *Armed Forces personnel.* A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the FEDERAL REGISTER the following information:

(A) Appropriate military command authorities; and

(B) The purposes for which the protected health information may be used or disclosed.

(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Homeland Security may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

(iii) *Veterans.* A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.

(iv) *Foreign military personnel.* A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the FEDERAL REGISTER pursuant to paragraph (k)(1)(i) of this section.

(2) *National security and intelligence activities.* A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (*e.g.,* Executive Order 12333).

(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized Federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056 or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

(4) *Medical suitability determinations.* A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual

DEPARTMENT OF STATE HEALTH SERVICES NOTICE OF PRIVACY PRACTICES

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

When you receive treatment or benefits from any Department of State Health Services (DSHS) facility or program, we receive, create and maintain information about your health, treatment, and payment for services. We will not use or disclose your information without your written authorization (permission) except as described in this notice.

HOW WE MAY USE AND DISCLOSE YOUR HEALTH INFORMATION

We may use and disclose your health information without your authorization for treatment, payment, and health care operation purposes. Examples include but are not limited to:

- Using or sharing your health information with other health care providers involved in your treatment or with a pharmacy that is filling your prescription.
- Using or sharing your health information with your health plan to obtain payment for services or using your health information to determine your eligibility for government benefits in a health plan.
- Using or sharing your health information to run our business, to evaluate provider performance, to educate health professionals, or for general administrative activities.

We may share your health information with our business associates who need the information to perform services on our behalf and agree to protect the privacy and security of your health information according to agency standards.

We may use or share your health information without your authorization as authorized by law for our patient directory, to family or friends involved in your care, or to a disaster relief agency for purposes of notifying your family or friends of your location and status in an emergency situation.

We may use and disclose your health information without your authorization to contact you for the following activities, as permitted by law and agency policy: providing appointment reminders; describing or recommending treatment alternatives; providing information about health-related benefits and services that may be of interest to you; or fundraising.

We may also use and disclose your health information without your authorization for the following purposes:

- For public health activities such as reporting diseases, injuries, births or deaths to a public health authority authorized to receive this information, or to report medical device issues to the FDA;
- To comply with workers compensation laws and similar programs;
- To alert appropriate authorities about victims of abuse, neglect, or domestic violence; if the agency reasonably believes you are a victim of abuse, neglect, or domestic violence we will make every effort to obtain your permission, however, in some cases we may be required or authorized to alert the authorities;
- For health oversight activities such as audits, investigations, and inspections of DSHS facilities;
- For research approved by an Institutional Review Board or privacy board; for preparing for research such as writing a research proposal; or for research on decedents information;
- To create or share de-identified or partially de-identified health information (limited data sets);
- For judicial and administrative proceedings such as responding to a subpoena or other lawful order;
- For law enforcement purposes such as identifying or locating a suspect or missing person;
- To coroners, medical examiners, or funeral directors as needed for their jobs;
- To organizations that handle organ, eye or tissue donation, procurement, or transplantation;
- To avert a serious threat to health or public safety;
- For specialized government functions such as military and veteran activities, national security and intelligence activities, and for other law enforcement custodial situations;
- For incidental disclosures such as when information is overheard in a waiting room despite reasonable steps to keep information confidential; and
- As otherwise required or permitted by local, state, or federal law.

Additional privacy protections under state or federal law apply to substance abuse information, mental health information, certain disease-related information, or genetic information. We will not use or share these types of information unless expressly authorized by law. We will not use or disclose genetic information for underwriting purposes.

We will always obtain your authorization to use or share your information for marketing purposes, to use or share your psychotherapy notes, if there is payment from a third party, or for any other disclosure not described in this notice or required by law. You have the right to cancel your authorization, except to the

extent that we have taken action based on your authorization. You may cancel your authorization by writing to the privacy officer per below.

YOUR PRIVACY RIGHTS

Although your health record is the property of DSHS, you have the right to:

- Inspect and copy your health information, including lab reports, upon written request and subject to some exceptions. We may charge you a reasonable, cost-based fee for providing records as permitted by law.
- Receive confidential communications of your health information, such as requesting that we contact you at a certain address or phone number. You may be required to make the request in writing with a statement or explanation for the request.
- Request amendment of your health information in our records. All requests to amend health information must be made in writing and include a reason for the request.
- Request an accounting (a list) of certain disclosures of your health information that we make without your authorization. You have the right to receive one accounting free of charge in any twelve-month period.
- Request that we restrict how we use and disclose your health information for treatment, payment, and health care operations, or to your family and friends. We are not required to agree to your request, except when you request that we not disclose information to your health plan about services for which you paid with your own money in full.
- Obtain a paper copy of this notice upon request.

You may make any of the above requests in writing to the DSHS privacy officer or your DSHS provider's privacy office. You can reach DSHS at (512) 776-7111 or (888) 963-7111 or by email at hipaa.privacy@dshs.texas.gov.To request results of lab tests performed by the DSHS lab, please call (512) 776-7318 or visit https://www.dshs.texas.gov/lab/patientresults.aspx.

OUR DUTIES

We are required to provide you with notice of our legal duties and our privacy practices with respect to your health information. We must maintain the privacy of information that identifies you and notify you in the event your health information is used or disclosed in a manner that compromises the privacy of your health information.

We are required to abide by the terms of this notice. We reserve the right to change the terms of this notice and to make the revised notice effective for all health information that we maintain. We will post revised notices on our public website at www.dshs.texas.gov and in waiting room areas. You may request a copy of the revised notice at the time of your next visit.

COMPLAINTS

If you feel that your rights have been violated:

- You may file a complaint by contacting the **DSHS Privacy Office** by mail at Mail Code 1919, P.O. Box 149387 Austin, TX 78714; by telephone at (512) 776-6502; or by email hipaa.privacy@dshs.texas.gov.

- You may also file a complaint by contacting the **Office for Civil Rights, Region VI, U.S. Department of Health and Human Services**, by mail at 1301 Young St., Suite 1169, Dallas, Texas 75202; by telephone at (800) 368-1019, (214) 767-0432 (fax), or (800) 537-7697 (TDD). You can also visit https://www.hhs.gov/ocr/privacy/hipaa/complaints.

For complaints about a violation of your right to confidentiality by an alcohol or drug abuse treatment program, contact the United States Attorney's Office for the judicial district in which the violation occurred.

We will not retaliate against you for filing a complaint.

Appendix F: Ordering Hepatitis B Biologicals and DSHS Specimen Submission

Ordering HBIG and Hepatitis B Vaccine from DSHS

To order emergency HBIG and/or hepatitis B vaccine for newborns, Texas DSHS, PHR and LHD offices must email the Texas PHBPP at TxPeriHepB@dshs.texas.gov with the following information:

- **The Provider Identification Number (PIN)**
- **Clinic Days and Hours:** List the hours the clinic will be open to accept vaccine shipments for each day of the week and note any lunch periods when no one is available to receive the vaccine. Be sure to note any holidays or clinic closings.
- **Contact Person:** Name of person who is physically present at the clinic to accept the shipment.
- **Phone:** Phone number of the contact person.
- **Clinic Address:** Provide complete name and address of clinic.
- **Pick from List:** Provide the vaccine needed and the vaccine formulation requested and the request for HBIG.
- **Order Amount:** Indicate number of doses needed.
- **Date of Order:** Date the order was completed.

Upon receiving a vaccine request, the DSHS PHBPP will forward the request to the Vaccine Management Group to submit the order in the Inventory Tracking Electronic Assets Management System (ITEAMS).

The order will be shipped via the DSHS Pharmacy Unit. The DSHS Pharmacy Unit ships orders on Monday, Tuesday, and Wednesday of each week. To meet shipping deadlines, orders must be received before 2:00 p.m. on these days. In the event of an emergency, please call the DSHS Immunization Section at 800-252-9152. For after hour emergencies, call the DSHS emergency telephone number 512-776-4911 and ask for the physician on-call then give the physician the information concerning your emergency.

Submitting Specimens to DSHS-Austin Laboratory

If your agency does not already have a submitter identification (ID), one must be created with the DSHS Laboratory prior to submitting specimens for testing. To request a submitter ID, the Submitter Identification (ID) Number Request Form should be completed. It is available at the DSHS laboratory website at www.dshs.state.tx.us/WorkArea/DownloadAsset.aspx?id=8589956433.
Once completed, the form should be faxed to 512-776-7533. Once the lab has received the completed form, a submitter ID will be created. Specimens cannot be shipped until a submitter ID has been acquired and given to your facility. For questions, please call 512-776-7578.
NOTE: Do not collect a specimen until you have a submitter ID, as this process may take several days to complete.

To submit a specimen for testing at the DSHS Laboratory after a submitter ID is obtained:

1. Complete the DSHS Specimen Submission Form (G-2A) for the corresponding sample. The information below is required for all specimens submitted to the DSHS Laboratory. Submissions missing any of the information below will not be processed. For additional guidance, a current sample of the G-2A submission form and detailed instructions is available at http://www.dshs.state.tx.us/lab/MRS_forms.shtm.
    - Section One
        - Submitter
            - Name
            - Submitter ID
            - National Provider Identifier (NPI) number
            - Address and contact information
    - Section Two
        - Patient identifiers
            - Name
            - Date of Birth
            - Medical records number
            - Address and contact information
        - Collection
            - Date and Time (must match the specimen)
    - Section 3
        - Specimen source (serum, plasma, etc.)
    - Section 7
        - Requested test(s): (check all boxes that apply)
            - Hepatitis B surface antibody (anti-HBs)
            - Hepatitis B surface antigen (HBsAg)
            - Hepatitis B core antibody (anti-HBc)
            - Hepatitis B core IgM antibody (IgM anti-HBc)

- Section 8
  - Ordering Physician Information (including NPI Number)
- Section 9
  - Payor Source
    - Immunizations

2. Retain a copy of the G2-A for your records.
   Tip: Keep a copy of the submission form in the patient's case management chart.
3. Clearly label the red top or tiger top tube and paperwork with:
   - Patient's full name and DOB
   - Date and time of collection
   - Initials of person collecting specimen

   - **NOTE**: All information (name, date, time) on the submission form must match the information on the specimen tube. If any information does not match, the specimen will be rejected, and no testing will be performed.
4. Obtain six-eight mL of venous blood (minimum of two mL) in a red top tube (serum tube) or tiger top tube (Serum Separator Tube [SST]).
5. Single or Separated Serum may be submitted; whole blood is not accepted.
6. The tiger top SST tubes cannot be frozen. If specimen needs to be frozen, remove the separated serum and place in a red top tube. If frozen, the date and time removed from the freezer must be noted in the section at the bottom right corner of the G-2A form.
7. Do not send specimens to be delivered on Saturday, as staff will not be available to receive deliveries.
8. Do not ship on Fridays or the day before state holidays. State holidays/closures can be found at http://www.hr.sao.texas.gov/Holidays.

Test	Specimen Type	Time allowed from collection to laboratory arrival	Temperature	Shipping Requirement
Anti-HBs HBsAg Anti-HBc IgM	Serum separated from the clot (red top or tiger top)	Up to 48 hours	Cold 2°C to 8°C	Ship on cold packs
	Serum separated from the clot (red top only)	Longer than 48 hours	Frozen -20°C or colder	Ship on dry ice

Table F.1. DSHS Lab Criteria for Hepatitis B Specimen Testing

Visit www.dshs.state.tx.us/lab/mrs_shipping.shtm for additional information on protocols for shipping biological specimens.

Visit www.dshs.state.tx.us/lab or call 512-776-7578 for additional information on protocols for shipping biological specimens.

Visit: www.dshs.state.tx.us/lab/ab_faqs.shtm for frequently asked questions (FAQs) about the laboratory.

Call 512-776-7578 to obtain laboratory results, status on laboratory tests, or to have a duplicate report sent.
Specimens and their G-2A form should be shipped by overnight carrier to:

Attn: Walter Douglass

Texas Department of State Health Services

Laboratory Services Section

1100 West 49th Street

Austin, Texas 78756-3194

Appendix G: Immunization Action Coalition Hepatitis B Birth Dose Honor Roll

FROM THE IMMUNIZATION ACTION COALITION

Do you qualify for the Hepatitis B Birth Dose Honor Roll?

If so, apply today.

The Immunization Action Coalition (IAC) is recognizing hospitals and birthing centers that have attained 90% or greater coverage rates for administering hepatitis B vaccine at birth and have met specific additional criteria. These criteria define the important elements of written birth dose policies aimed at protecting newborns, including when medical errors occur.

Criteria for Inclusion into the Honor Roll

To be included in IAC's Hepatitis B Birth Dose Honor Roll, a birthing institution must have:

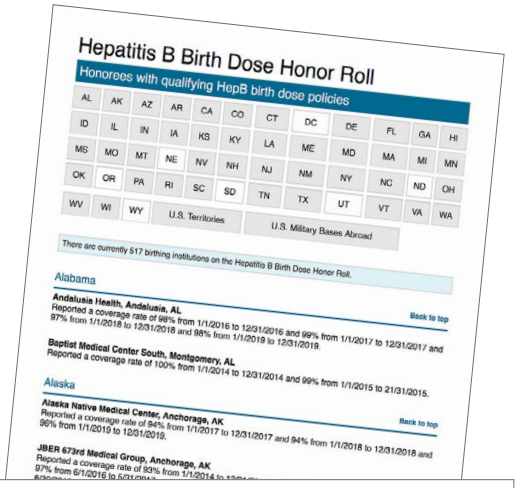
- ☑ Achieved, over a 12-month period, a coverage rate of 90% or greater for administering hepatitis B vaccine before hospital discharge to all newborns (regardless of weight), including those whose parents refuse vaccination, and
- ☑ Implemented certain written policies, procedures, and protocols to protect all newborns from hepatitis B virus infection prior to hospital discharge.

To apply for the Birth Dose Honor Roll, visit

www.immunize.org/honor-roll/birthdose

Benefits

- Inclusion in online Honor Roll
- Announcement of achievement in nation's largest immunization e-newsletter, *IAC Express*, sent to approximately 50,000 subscribers
- Receipt of beautiful 8.5" x 11" color award certificate suitable for framing
- Peer recognition in the immunization community


Hepatitis B Birth Dose Honor Roll

Honorees with qualifying HepB birth dose policies

AL AK AZ AR CA CO CT DC DE FL GA HI ID IL IN IA KS KY LA ME MD MA MI MN MS MO MT NE NV NH NJ NM NY NC ND OH OK OR PA RI SC SD TN TX UT VT VA WA WV WI WY U.S. Territories U.S. Military Bases Abroad

There are currently 517 birthing institutions on the Hepatitis B Birth Dose Honor Roll.

Alabama

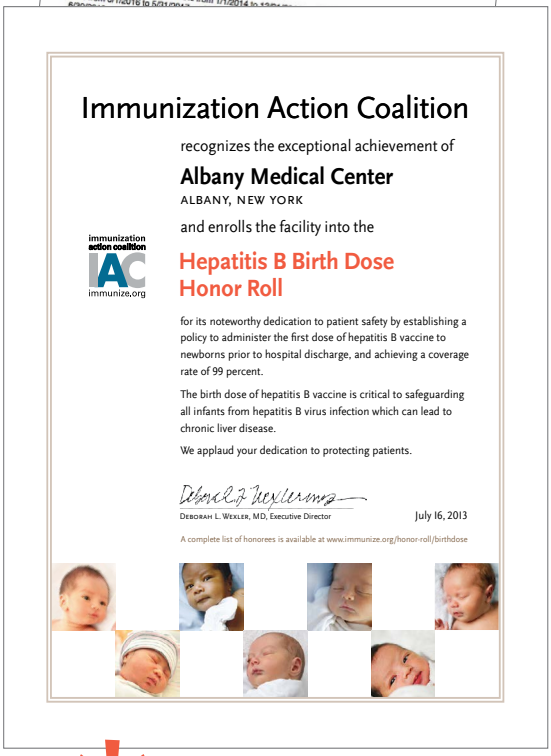
Andalusia Health, Andalusia, AL
Reported a coverage rate of 98% from 1/1/2016 to 12/31/2016 and 99% from 1/1/2017 to 12/31/2017 and 97% from 1/1/2018 to 12/31/2018 and 98% from 1/1/2019 to 12/31/2019.

Baptist Medical Center South, Montgomery, AL
Reported a coverage rate of 100% from 1/1/2014 to 12/31/2014 and 99% from 1/1/2015 to 21/31/2015.

Alaska

Alaska Native Medical Center, Anchorage, AK
Reported a coverage rate of 94% from 1/1/2017 to 12/31/2017 and 94% from 1/1/2018 to 12/31/2018 and 96% from 1/1/2019 to 12/31/2019.

JBER 673rd Medical Group, Anchorage, AK
Reported a coverage rate of 93% from 1/1/2014 to


Immunization Action Coalition

recognizes the exceptional achievement of

Albany Medical Center

ALBANY, NEW YORK

and enrolls the facility into the

Hepatitis B Birth Dose Honor Roll

for its noteworthy dedication to patient safety by establishing a policy to administer the first dose of hepatitis B vaccine to newborns prior to hospital discharge, and achieving a coverage rate of 99 percent.

The birth dose of hepatitis B vaccine is critical to safeguarding all infants from hepatitis B virus infection which can lead to chronic liver disease.

We applaud your dedication to protecting patients.

Deborah L. Wexler, MD, Executive Director — July 16, 2013

A complete list of honorees is available at www.immunize.org/honor-roll/birthdose

The universal hepatitis B vaccine birth dose is supported by leading health organizations

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American College of Obstetricians and Gynecologists (ACOG)
- Centers for Disease Control and Prevention (CDC)

Immunization Action Coalition Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p2205.pdf • Item #P2205 (9/20)

Texas Hospitals Enrolled in the Immunization Action Coalition (IAC) Hepatitis B Birth Dose Honor Roll

Facility	City	Years Qualified
Ben Taub Hospital	Houston	Two
Baylor, Scott & White Medical Center-Brenham	Brenham	Two
Baylor, Scott & White Medical Center-College Station	College Station	Three
Baylor, Scott & White Medical Center-Lakepointe	Rowlett	One
Baylor, Scott & White Medical Center- Marble Falls	Marble Falls	One
Baylor, Scott & White Medical Center- Round Rock	Round Rock	One
Baylor, Scott & White Medical Center-Waxahachie	Waxahachie	Three
Big Bend Medical Center	Alpine	Two
Brownfield Regional Medical Center	Brownfield	Two
BSA Health System	Amarillo	Two
CHI St. Joseph Health Bryan	Bryan	Two
CHI St. Luke's Health Memorial	Lufkin	One
Childress Regional Medical Center	Childress	One
CHRISTUS Mother Frances Hospital - Sulphur Springs	Sulphur Springs	Three
CHRISTUS Spohn Hospital Kleberg	Kingsville	One
CHRISTUS St. Michael Health System	Texarkana	One
Cogdell Memorial Hospital	Snyder	Four
Coleman County Medical Center	Coleman	One
Columbus Community Hospital	Columbus	Two
Coon Memorial Hospital	Dalhart	One
Covenant Children's Hospital	Lubbock	One
Covenant Hospital Levelland	Levelland	One
Covenant Hospital Plainview	Plainview	Three

Facility	City	Years Qualified
Del Sol Medical Center	El Paso	One
Doctors Hospital of Laredo	Laredo	One
East Texas Medical Center Jacksonville	Jacksonville	Two
Golden Plains Community Hospital	Borger	Two
Good Shepherd Medical Center Marshall	Marshall	One
Goodall-Witcher Health care Foundation	Clifton	One
HCA The Women's Hospital of Texas	Houston	Two
Hendrick Medical Center	Abilene	One
Hereford Regional Medical Center	Hereford	One
Hill Regional Hospital	Hillsboro	Two
The Hospitals of Providence-East Campus	El Paso	One
The Hospitals of Providence-Memorial Campus	El Paso	One
The Hospitals of Providence-Sierra Campus	El Paso	One
The Hospitals of Providence Transmountain Campus	El Paso	One
Houston Methodist Hospital	Houston	Two
Houston Methodist ST. John Hospital	Nassau Bay	Two
Houston Methodist Sugarland Hospital	Sugarland	One
Houston Northwest Medical Center	Houston	One
Hunt Regional Medical Center Greenville	Greenville	One
Lake Granbury Medical Center	Granbury	One
Lamb Health care Center	Littlefield	One
Las Palmas Medical Center	El Paso	One
Lyndon B. Johnson General Hospital	Houston	Four
Medical Arts Hospital	Lamesa	One
Medical Center Hospital Odessa	Odessa	One

Facility	City	Years Qualified
Memorial Hermann Pearland Hospital	Pearland	Two
Memorial Hermann Southeast Hospital	Houston	Four
Memorial Hermann Southwest Hospital	Houston	Two
Methodist Dallas Medical Center	Dallas	Two
Methodist San Jacinto Hospital	Baytown	Two
Midland Memorial Hospital	Midland	One
Moore County Hospital	Dumas	One
Nacogdoches Medical Center	Nacogdoches	One
North Texas Medical Center	Gainesville	One
Ochiltree General Hospital	Perryton	Two
Odessa Regional Medical Center	Odessa	Two
Olney Hamilton Hospital	Olney	Three
Palo Pinto General Hospital	Mineral Wells	Five
Pampa Regional Medical Center	Pampa	One
Pecos County Memorial Hospital	Fort Stockton	One
Reeves County Hospital District	Pecos	One
Rio Grande Regional Hospital	McAllen	One
Rolling Plains Memorial Hospital	Sweetwater	One
Scenic Mountain Medical Center	Big Spring	Two
Seminole Memorial Hospital	Seminole	Three
Seton Medical Center Williamson	Round Rock	One
Seymour Hospital	Seymour	One
Shannon Medical Center	San Angelo	Four
St David's Georgetown Hospital	Georgetown	Two
St. David's Round Rock Medical Center	Round Rock	Four
St. David's South Austin Medical Center	Austin	Two
Starr County Memorial Hospital	Rio Grande City	Two

Facility	City	Years Qualified
Texas Children's Hospital	Houston	One
Texas Health Harris Methodist Hospital	Stephenville	One
Texas Health Huguley-Fort Worth South	Fort Worth	Three
Texas Health Rockwall	Rockwall	Two
Texoma Medical Center	Denison	One
Tomball Regional Medical Center	Tomball	One
United Regional	Wichita Falls	One
UTMB Health Angleton-Danbury Campus	Angleton	One
Valley Baptist Medical Center Brownsville	Brownsville	Three
Wadley Regional Medical Center	Texarkana	One
Weatherford Regional Medical Center	Weatherford	One
William Beaumont Army Medical Center	El Paso	One
Wilson N. Jones Regional Medical Center	Sherman	Two
Yoakum County Memorial Hospital	Denver City	Four

Appendix H: Frequently Asked Questions

1. What should we do when we get discrepant lab results for cases? (i.e., when a prenatal HbsAg lab is positive and the delivery HbsAg lab is negative?)

   Women who have had ANY confirmed positive HBsAg lab result should be case managed and their infants should receive Post-Exposure Prophylaxis (PEP) at birth. They should be case managed until HBsAg status is confirmed. To determine chronic hepatitis B, the client needs to have two positive HBsAg results at least six months apart. Clients with discrepant labs should be tested for HBsAg, Anti-HBs and Anti-HBc. This will help differentiate between acute and chronic hepatitis B cases. In addition, getting the vaccine history can help determine if they had a false positive HbsAg result.

2. When should I close out an index case as "referred for medical follow up" and how do I do that?

   Referred for medical follow-up means that the case manager has instructed the index case to follow-up with their PCP or specialist for management of hepatitis B. Case managers do not need to get an actual referral for the client. Any index case with chronic hepatitis B can be closed as "referred to medical follow up," as long as they have been educated about the need for regular hepatitis B monitoring and advised to see their specialist/PCP.

3. What should we do if postvaccine serology testing (PVST) for an infant is done before the infant is nine months of age?

   Completing PVST prior to nine months of age is not recommended, as it can lead to inaccurate results due to the detection of passive anti-HBs from the HBIG administered at birth. Also, testing after nine months of age will increase the chance of detecting a late hepatitis B infection. If an infant completes testing early, they should be re-tested again after nine months of age to ensure accurate results. Education should be given to the provider about the need to wait until the infant is over nine months of age to perform PVST.

4. I have pediatric providers who want to wait to do PVST at one year of age. How should I respond to this?

   Case managers should educate providers on why completing PVST at nine months of age is optimal for the child's health and safety. Infants who complete the hepatitis B vaccine series on time should have PVST done at nine months of age to capture any late-occurring hepatitis B infections, while avoiding inaccurately sensing passive anti-HBs still circulating from the HBIG given at birth. PVST at nine months of age is also convenient because the infant is due for a well-child check-up.

   Waiting to perform PVST until the child is older can result in false-negative Anti-HBs results and more vaccines for the infant. In addition, infants who do not respond to the first series of vaccines are still susceptible to hepatitis B and are at high risk of exposure in their household. It is imperative that the susceptible infants are re-vaccinated immediately to prevent hepatitis B transmission. Also, there are occasional cases of perinatal hepatitis B infection, despite PEP, and these infants need to be evaluated and reported as soon as possible.

5. What should we do when we have cases that are not responding to calls/letters?

   Utilize all available resources to check for updated contact information, including providers, NEDSS, ImmTrac2, and Medicaid/WIC, as applicable. Ask the provider if they have received a record request from another provider or know of any plans to move out of the country or out of the state. Follow the instructions listed in Chapter 9: Case Management to establish contact with the client. Do not close out as "never located" or "lost to follow-up" without following the steps listed in the manual. If unable to establish contact after following the steps listed in the manual, contact your coordinator for advice on how to close the case.

6. What are some strategies to educate providers?

   Provider education and training is a vital component of the Texas DSHS PHBPP. It is the responsibility of the case managers to provide training to prenatal providers, labor & delivery staff, and pediatricians. These providers all need to be aware of the state laws and statutes related to HbsAg testing and reporting, serology interpretation, recommended PEP, how to handle mothers with an unknown status, and the hepatitis B vaccine series and PVST.

   There are various ways to provide training. An in-person training is best for new providers or new labor and delivery staff. See the training checklist for details of topics and materials for each type of training. In-person training may also be needed after there is a missed HBsAg screen, PEP, etc., to review the facility's policies and procedures.

7. Can you explain what is different for infants who weigh less than 2,000 grams (4.4 lbs.) at birth?

   Infants who weigh less than 2,000g at birth (less than 4.4 lbs.) are considered low birthweight infants (LBW). LBW infants born to HbsAg-positive mothers should receive HBIG and the birth dose of HBV within 12 hours of birth, however, the HBV birth dose does not count toward the vaccine series because LBW infants may have decreased immunogenicity. These infants should complete the three additional doses according to ACIP's vaccine recommendation schedule and will need to receive at least four total doses of the hepatitis B vaccine. Ensure LBW infants are flagged/noted in the case management tracking system to confirm the infants receive the appropriate number of hepatitis B vaccine doses.

   NOTE: LBW infants born to women of unknown HBsAg status should receive HBIG and the hepatitis B vaccine within 12 hours of birth as well.

   LBW infants born to HbsAg-negative mothers can have their first hepatitis B vaccine deferred by the provider until one month of age or hospital discharge.

8. What should we do if we have a HbsAg positive mother who refuses post-exposure prophylaxis for her infant?

   It is important to provide education to the mother prior to the infant's birth about the potential consequences of perinatal hepatitis B infection and how to prevent transmission. Use real-life personal stories about hepatitis B to illustrate the importance of prevention. The Hepatitis B Foundation (hepb.org) has short videos of people sharing their experiences with hepatitis B. If a mother still refuses PEP after delivery, the hospital should require the mother to sign a refusal to vaccinate/against medical advice form. Obtain a copy of the refusal documentation for the case management file. Obtain information for the infant's pediatrician and follow up at their two month visit to see if the mother consented to the hepatitis B vaccine. If not, close out the case as "noncompliant/refused."

   Generally, involving child protective services or another authoritative figure has not been successful in convincing these mothers to consent to PEP. Providing real-life examples and stories may help convince a hesitant mother to allow PEP.

9. I have an index case who has moved out of my jurisdiction, what should I do?

   First, review the Case Management Report (CMR) for completion prior to transferring. Close out the case appropriately, for example as "transferred to another jurisdiction", "transferred to San Antonio/Houston", or "moved out of state". There does not need to be any transfer form completed if the client moves out of the country. Make sure to document the case's new address and contact information in the comment section. Complete the ***Case Management Transfer Form*** (Stock no. F11-11015) and send that form along with the CMR(s) to your PHR coordinator. Central Office (CO) is responsible for sending the case to the appropriate jurisdiction.

   If you discover the client has moved out of the state but are unable to obtain the new address, contact CO for assistance. CO can contact the other state to see if they are able to find the case. If the other state cannot find an address, the case will have to be closed as "lost to follow-up" instead of "transferred out of state". Remember that all transfers out of state need to be done by CO.

10. I just received PVST results for one of my cases, but the provider only performed one lab test instead of both. What should I do?

    First, check the date of when the lab was performed. Most commercial labs keep specimens for four or five days and may be able to add labs to an existing specimen. If the lab was recent, immediately call the provider and ask them to call the lab and add the other test to the specimen.

    If it has been more than a week, notify the provider and explain why both labs need to be completed. The provider should notify the guardian to return with the infant for additional testing.

    Some providers may not feel it is necessary to repeat a lab draw for one missing lab. Reiterate the need for both labs to ensure the infant is not infected and that vaccination was successful.

11. I have an anti-HBs result for an infant that is less than 10 IU/mL or non-reactive. What should we do?

    First, make sure the HbsAg lab was drawn along with the anti-HBs to rule out an HB infection. If the HbsAg is also negative, this infant is considered "susceptible." The infant should receive a booster dose of hepatitis B vaccine immediately. The infant can then repeat PVST (HBsAg and Anti-HBs) one to two months after the booster dose. If the anti-HBs remains non-reactive after the booster dose, the infant should repeat an entire second hepatitis B vaccine series and needs two more doses of hepatitis B vaccine. The infant should then repeat PVST one to two months after the last vaccine. The CDC recently recommended this booster dose option based on studies that found that children showed an adequate immune response (anti-HBs 10 mIU/mL or greater) after just one hepatitis B vaccine.

    The guardian and provider can also choose to immediately repeat the entire three-dose hepatitis B vaccine series and repeat PVST one to two months after the last vaccine.

12. I have an infant who has received three doses of hepatitis B vaccine, but the last dose was given at four months of age. Is this infant considered complete?

    No, this infant needs another dose of hepatitis B vaccine, on or after six months of age.

13. Any tips for finding infants in ImmTrac?

    ImmTrac2 has a "smart search" function. You do not need to know the name of the infant to use this function. Instead, you can put in "baby" and "girl" for the first and last name section. Then, put in the appropriate birthday, sex, and street address. This can help find infants when their first and last names are unknown. ImmTrac2 also has instructional videos and webinars online at www.dshs.texas.gov/immunizations/health-departments/training.

14. I received a delivery report with no known mother information. The hospital says the infant was safely surrendered. What should I do and how can I case manage without the mother's information?

    The CDC recommends that all infants born to women whose hepatitis B status remains unknown indefinitely (e.g., safely surrendered after birth) be enrolled in PHBPP. These infants will need to receive HBIG and the hepatitis B birth dose, complete the Hepatitis B vaccine series, and complete PVST.

    If you receive a delivery report for an infant that was safely surrendered, contact the hospital, and ask to speak with the infant's social worker. The social worker should have information about the child's placement (e.g., with a foster family, with relatives etc.) and their contact information. Once the contact information is received, reach out to the responsible guardians, and tell them about PHBPP and the need for case management. The "mother's case management report" can be completed without knowing the mother's information. For example, use "Jane Doe" for the mother's name and leave all other information blank. Write a note in the comment section that this was a safe surrender infant. Open the infant CMR and use the guardian's demographic information for the "phone number" and "address" fields. Make a note that this is a safe surrender infant.

15. Should HBsAg positive pregnant also have HBV DNA testing?

    Yes, the CDC recommends that HBsAg positive pregnant women also be tested for HBV DNA. The test is used to guide antiviral therapy that might be indicated for women with very high HBV DNA viral loads.

16. How can I help my hospitals enroll in IAC's Hepatitis B Honor Roll?

    The ***Hepatitis B Birth Dose Honor Roll*** recognizes U.S. birthing institutions with a birth dose coverage rate of 90% or greater and who have also met additional criteria to ensure newborns do not fall through the cracks in the event of a medical error. Application for Honor Roll inclusion is available at www.immunize.org/honor-roll/birthdose/apply.aspx.

17. What types of support are available for these mothers?

    The DSHS Immunization Section PHBPP has developed educational materials for HBsAg-positive women and their health care providers. These materials can be found at www.texasperinatalhepb.org.

    The CDC and the organization Hep B Moms have information about hepatitis B and perinatal hepatitis B available to order for free or to download in many different languages from: www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm#eduTools and https://www.hepbmoms.org/copy-of-about.

Footnotes

1. Under Texas law, both acute and chronic infection of hepatitis B in a pregnant woman are conditions that must be reported to the DSHS. The Texas Health & Safety Code Title 2, Chapter 81 authorizes LHDs to conduct disease investigations and gather all pertinent medical information.
2. Numbers are not inclusive of City of Houston and City of San Antonio.
3. Under Texas law, both acute and chronic infection of hepatitis B in a pregnant woman are conditions that must be reported to the DSHS. The Texas Health & Safety Code Title 2, Chapter 81 authorizes LHDs to conduct disease investigations and gather all pertinent medical information.

www.dshs.texas.gov/immunizations/what-we-do/vaccines/PHBPP

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